REF 888627R

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Appendix A: Error Conditions

**Patient, as defined in this manual, is synonymous with subject/sample, as in the person or thing that is being discussed or described.

Chapter 1: Introduction

Welcome to LIFECODES MATCH IT! Antibody Software. LIFECODES MATCH IT! Antibody Software is an accessory for the evaluation of test results from LIFECODE's antibody products.

The LIFECODES MATCH IT! Antibody Software is an aid to assist qualified laboratory personnel by suggesting the presence or absence of HLA antibodies. Due to the complex nature of HLA Testing, qualified laboratory personnel must review any result to assure correctness. The software is a laboratory aid and not meant to be the sole source of a definitive result.

System Requirements

The following is required to successfully install and use LIFECODES MATCH IT! Antibody Software, version 1.2.1, (Part Number 888627R).

Computer Requirements

- Microsoft™ Windows XP SP3, Vista, or Win 7 (32-64 bit version) operating systems
- Pentium® 4 or Core 2 Duo
- 10 GB hard disk space
- 4 GB RAM
- 24-bit graphics adapter and display
- XGA display with 1024 x 768
- Mouse or other windows compatible pointing device

Software Requirements

- Microsoft™ SQL Express 2008 (Included with software)
- Microsoft .NET Framework Version 3.5 (Included with software)
- (Optional) Microsoft™ SQL Server 2008 or 2012 for increased storage capacity

Luminex Requirements

- The LIFECODES MATCH IT! Antibody Software is designed to import csv files created by the Luminex 2.3 and xPONENT software versions.
- The data present in the csv file must be generated using an unmodified Luminex template provided by LIFECODES.

Networking

Networking Client Computers to a SQL Server

For Standard or Enterprise editions

1) From the **Start** Menu, Open the MATCH IT! database management utility drop-down. Choose the application and log-in required for this utility.

2) Click **Choose Server**.

3) Click **Available SQL Instances** dropdown to display known SQL instances.

4) Choose the SQL instance that contains the database.

5) Once the connection is established a list of available databases will be displayed. Choose the database and click **Ok** to connect.

6)Open Matchit Software.

Troubleshooting

If the SQL instance does not appear in the dropdown then there are two options:

1) Type in the name of the SQL instance, if the instance is valid and Match IT! can connect to it then the databases it holds will be listed. Click **Connect** to establish the connection.

2) Click **Refresh Server List** to scan the network for Match IT! instances.

If the SQL instance appears but Match IT! can not connect to it:

1) Check to see if a port for the instance has been specified.

Ask the database administrator to check the port settings in SQL Server Configuration Manager.

2) If a port has been specified then add the port number to the SQL instance in the dropdown.

Example:
<Computer name>, <port number>
MatchITserver, 1500

Networking Client computers to a SQL Server Express

For 2008 editions

1) From the **Start** Menu, Open the MATCH IT! database management utility drop-down. Choose the application and log-in required for this utility.

2) Click **Choose Server**.

3) Click **Available SQL Instances** dropdown to display known SQL instances.

4) Choose the SQL instance that contains the database. Click **Connect** to establish the connection.

5) Once the connection is established a list of available databases will be displayed. Choose the database and click Ok to connect.

Troubleshooting

On the computer that holds the database, verify the SQL Browser is off and TCP/IP is enabled.

Checking the SQL Browser state:

1) Open SQL Server Configuration Manager.

2) Click **SQL Server Services**.

3) Check that the SQL Server Browser is stopped. If it is not then, right click the service and choose stop.

Checking TCP/IP state:

1) Open SQL Server Configuration Manager.

2) Click **SQL Server Network Configuration**.

3) Click the correct protocol. This will be the name of the instance that holds the database.

4) Verify the status of TCP/IP. It should be enabled. If it is not then, right click TCP/IP and choose Enable.

If the SQL instance does not appear in the dropdown then there are two options:

1) Type in the name of the SQL instance, if the instance is valid and Match IT! can connect to it then the databases it holds will be listed.

2) Click **Refresh Server List** to scan the network for Match IT! instances.

If the SQL instance appears but Match IT! can not connect to it:

1) Check to see if a port for the instance has been specified.

2) Open SQL Server Configuration Manager.

3) Click **SQL Server Network Configuration**.

4) Click the correct protocol. This will be the name of the instance that holds the database

5) Double click **TCP/IP**.

6) Choose the IP Addresses tab.

7) Scroll to the bottom to find IPAll.

8) Check the TCP Port field. If a port has been specified then add the port number to the SQL instance in the dropdown.

Example:
<Computer name>, <port number>
MatchITserver, 1500

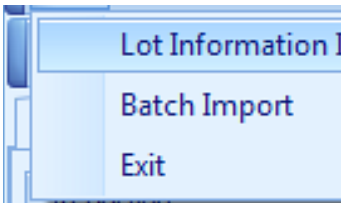
Note: Images depicted in this manual may differ slightly from MATCH IT! Antibody software. Please contact LIFECODES technical support with any questions.

CHAPTER 2: MATCH IT! MENUS

This chapter provides descriptions of the home menu functions. Menu functions which can be found on the main home screen are described in brief with a link to more detailed instructions. Other functions found only in the menu are described in this chapter in full detail.

Menus

File Menu



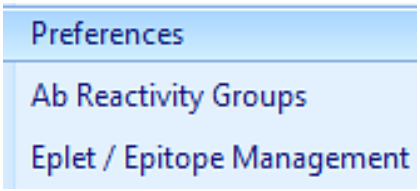
The *File Menu* contains addtional access to common functions found on the home screen. It allows the user to utilize keyboard shortcuts.

Lot Information Import: Access to importing specific lot information (EDS file). *See "Importing EDS files into MATCH IT!"*

Batch Import: Access to manually importing a csv file from a specified location. *See "Manually Importing CSV Files"*

Exit: Ability to exit the software.

Settings (Lab Settings) Menu



The *Settings Menu* contains laboratory defined settings for the various assays.

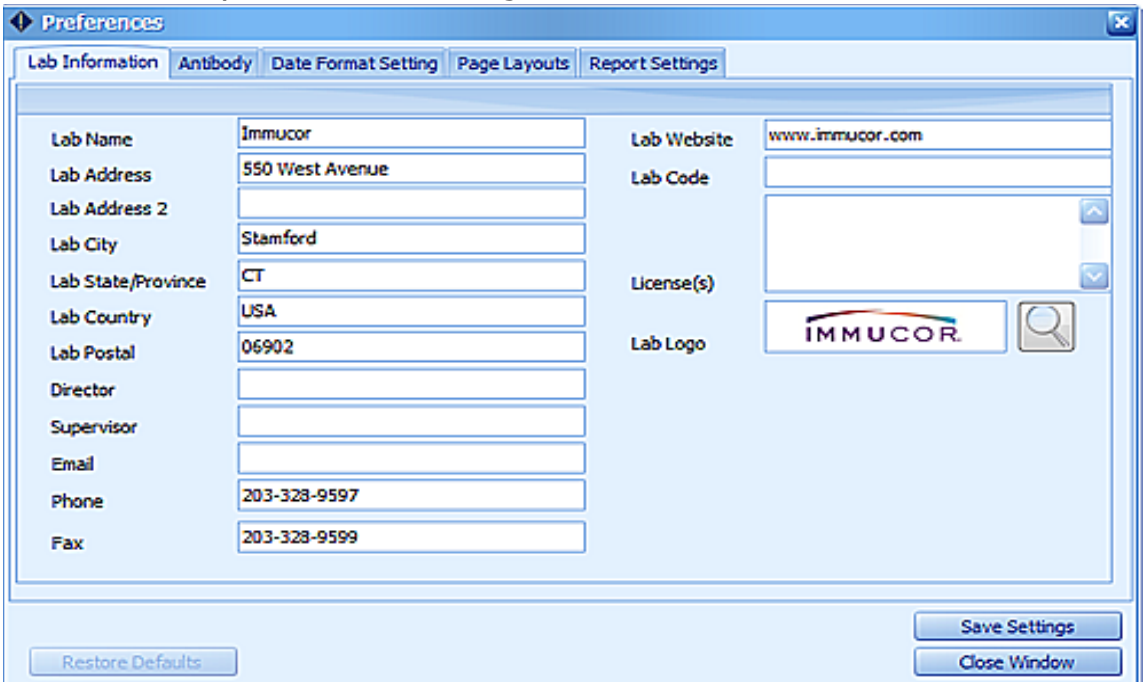
Preferences

This menu item contains several tabs for personal laboratory settings.

1) **Lab Information tab:** The user can input personal laboratory information. This is required information.

2) **Antibody tab:** This tab contains an individual tab for each antibody assay. Each assay specific tab includes analysis settings. The software is installed with default values for analysis. The default settings should only be altered by personnel knowledgeable in the field of HLA Antibody Analysis. Changing these values will result in altered specificity and sensitivity of the assay. The values may be changed using the up and down arrows next to the value, or by manually entering the value of choice. Once the

values have been entered, they can be saved by clicking **Save Settings**. If at any time default settings need to be restored, click **Restore Defaults**.



The specific functions of these settings are as follows.

Antibody Parameters*:*

a) The **Assign Cutoff** *(LifeScreen Deluxe, ID, LSA, C3d and DSA)* is a score of 1 to 4 for ID and DSA or a score of 1 to 3 for Screen, LSA, and C3d. It indicates the number of calculations, against different controls, that must be positive for the sample to be assigned as positive. This allows the user to show samples are positive with only 1 control, 2 controls, 3 controls, or all 4 controls. *The default setting is 2 for Screen supplemental beads, ID, LSA, C3d, and DSA. The default setting is 1 for Screen pooled bead. Changing this number will allow the user to chose how many controls need to be positive in order for the bead or analyte to be positive.*

b) The **Assign Adjust 1, 2, & 3** *(LifeScreen Deluxe, ID, and DSA)* **BCM, BCR, and AD-BCR** *(LSA only), and* ***BGA, BCM, and R-Strength*** *(C3d Only)* is the value used by the software to determine if a bead value is positive. This value sets the positive threshold for the adjusted value. *The default adjustment is 0 for all but LSA and C3d, which have lot-specific default adjustments. When an Adjusted Value (Adj Val 1, 2 and 3 or BCM, BCR, and AD-BCR), or BGA, BCM, and R-Strength) exceeds the Assign Adjust value, the Adjusted Value is considered positive. Thus, by raising the Assign Adjust, the assay sensitivity is reduced.*

c) The **Pos/Neg Control Override** *(LifeScreen Deluxe only when submitting batches to Liquid Handler)* allows the logged-in user to decide if this function should be enabled. When enabled, the entire batch is tied to the performance of the Positive and Negative control. All samples will be listed as failed if either the Positive or Negative Control samples fail.

- A Negative Control is considered as failed if any bead fails to meet the minimum bead count, or if the Negative Control has a positive assignment for Class I or Class II.
- A Positive Control is considered as failed if any bead fails to meet the minimum bead count, or if either of the Class I or Class II assignment is negative.

d) **Enable VBAF Calculation** *(LMX only)* allows the logged-in user to activate this feature. By default, this feature is inactivated. *VBAF*, or *Variable Background Adjustment Factor*, is designed to be used by personnel knowledgeable in the field of HLA Antibody analysis when the samples being analyzed have negative control bead values that do not conform to expected values. This calculation uses the following formula:

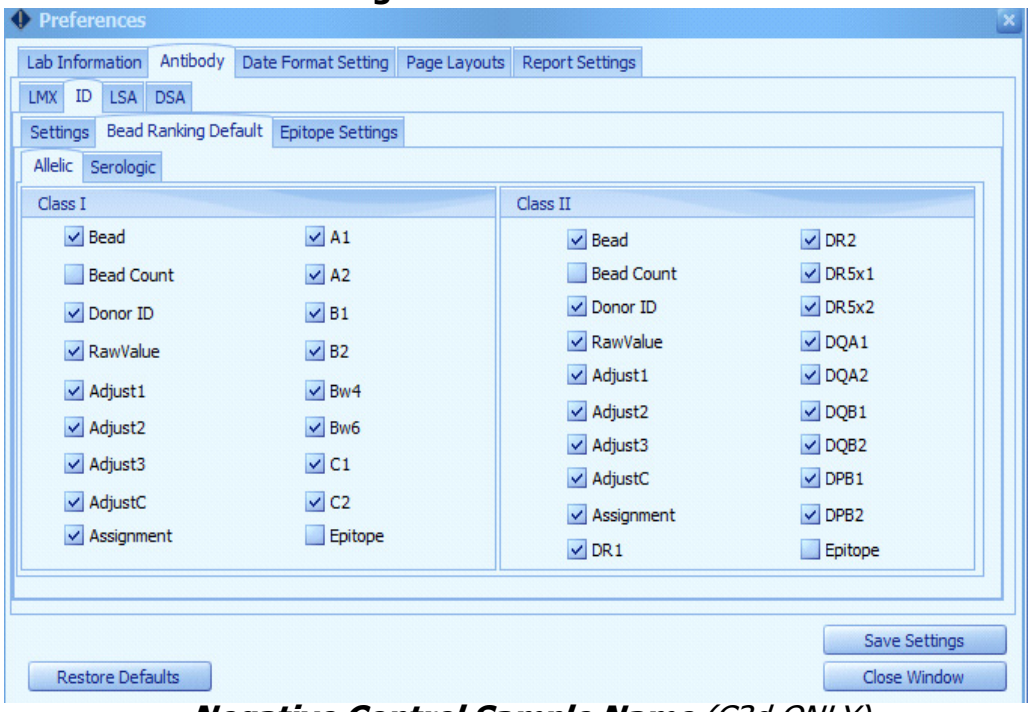
$$\mathbf{(MFI_{ClassI} - VBAF)/AVG_{CON1}\text{-}BAF_{CON1}\text{-}VBAF/256}$$

The *Variable Background Adjustment Factor (VBAF)* is calculated as the difference between the observed MFI for a CON bead and a predetermined average (AVG) value based on a set of negative sera. The VBAF is then subtracted from the MFI value of the CON and the Class 1 & Class II beads. VBAF makes the assay less sensitive when the negative control bead values are low and more sensitive when the negative control bead values are high. Once this feature is enabled, the calculation can be applied to an entire batch, or to individual samples. If the VBAF calculation is used, the sample header will indicate this. *By default this feature is inactivated.*

e) **Import Mode** *(ID and LSA)* allows the user to choose to apply either the Standard Assignment adjustments (Assign Cutoff and Assign Adjust or BCM, BCR and AD-BCR) or to set cut-offs based on an MFI value for ID and LSA files upon import.

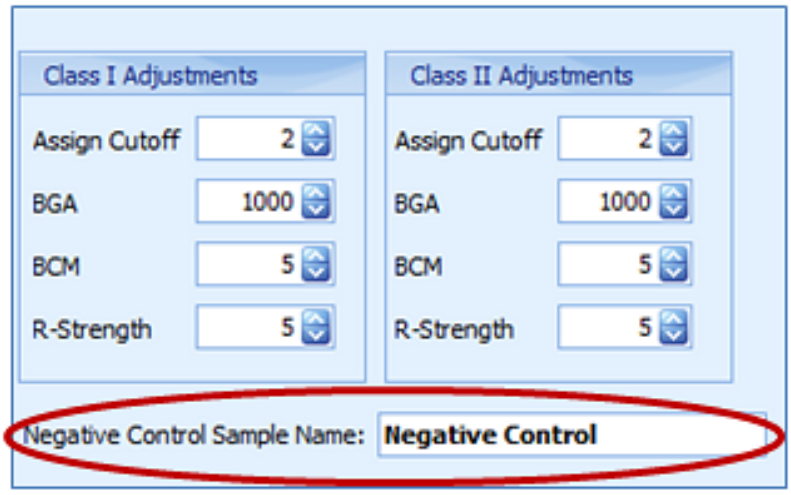
f) **Bead Ranking Default** tab (*(ID and LSA)* allows the user to define the columns that will be included on the *Bead Ranking Report* during export. The user can select individual columns by placing a

check next to the item. Once all items have been selected, click **Save Settings**.

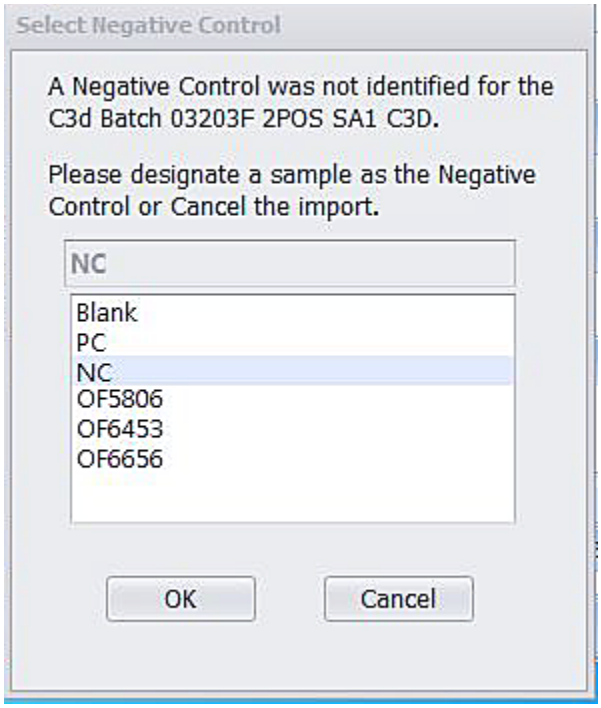


Negative Control Sample Name *(C3d ONLY)*

It is a requirement of the C3d assay that a negative control sample be included in every batch. The user must designate a *Negative Control Sample Name* that will be referenced for all C3d batches upon import.

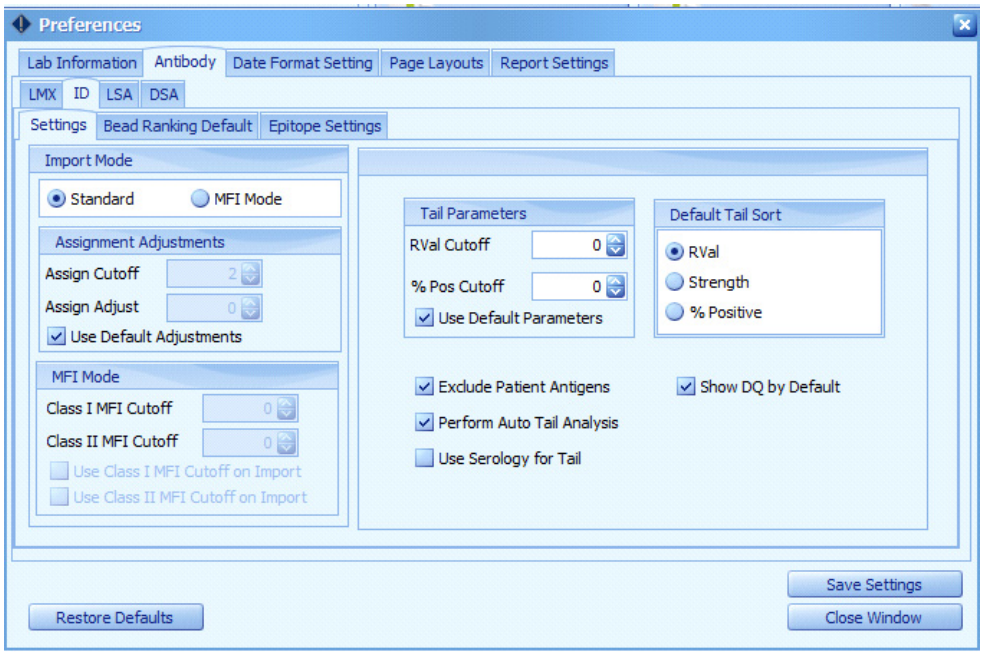


If the *Negative Control Sample Name* in the batch does not match what is listed in *Preferences*, the user will be prompted to select a negative control upon import.



The user must click on a sample from the list displayed in the dialogue box and then click **OK**.

Tail Parameters *(ID only):*



a) The **Rval Cutoff** is a score of 0 to 1. In the tail analysis, the software will display all antigens with an R-value greater than or equal to the cutoff set. *The default setting is 0.*

b) The **% Pos Cutoff** is a score of 0 to 100%. In the tail analysis, the software will display all antigens with a % positive score greater than or equal to the cutoff set. The % positive score represents the percentage of beads containing a particular antigen that are positive. *The default setting is 50.*

c) The **Tail Sort** feature allows the user to define the parameter by which to rank the antigens. *The default setting is RVal.*

d) For the software to automatically perform a tail analysis when opening the batch for the first time, check **Perform Auto Tail Analysis**.

e) If a 2-digit (serology) tail analysis is preferred as opposed to the 4-digit(Allelic), check **Use Serology for Tail**.

f) To always have the DQ enhanced beads (LM2Q) displayed in the bead ranking report, check **Show DQ by Default**

Analysis Options:
The user has the ability to perform **Auto Eplet Analysis** (ID and LSA) in the **Eplet Settings** tab. Once the **Auto Eplet Analysis** is selected, the appropriate parameters can then be chosen to analyze the data.

*Note: The **Auto Eplet Analysis** feature is not available for use if **Use Serology for Tail** is turned on.*

Additional Preferences:

a) **Exclude sample antigens** The user has the ability to **Exclude Antigens** on import if this information in entered during Automated Batch Set-up (ID and LSA).

To Exclude Antigens for ID, the **Exclude Patient Antigen** box must be checked on the Settings tab in ID.

To Exclude antigens for LSA, the **Exclude Patient Antigens** box must be checked on the Settings tab in LSA and the import **Exclude Antigen CSV file** (available from the Immucor website) must be imported in to the software

Note: *The sample's HLA type must be entered into the sample list or added to the* ***Sample Profile*** *in* ***Patient View*** *in order to display on the report. This feature is designed for batches submitted to Luminex through the MATCH IT! software. In order for antigens to be excluded they must match an antigen listed on the product worksheet and be separated by commas.*
Example:
A2, A24, B56, B51
or
*A*02:01, A*24:02, B*56:01, B*51:01*

b) **Override Default Adjustments** *(LSA and C3d only)* allows the user to set new cutoffs and apply them to all future batches of a given lot. When this box is left un-checked lot-specific cut-offs will be applied when in Standard Mode. This box is unchecked by default.

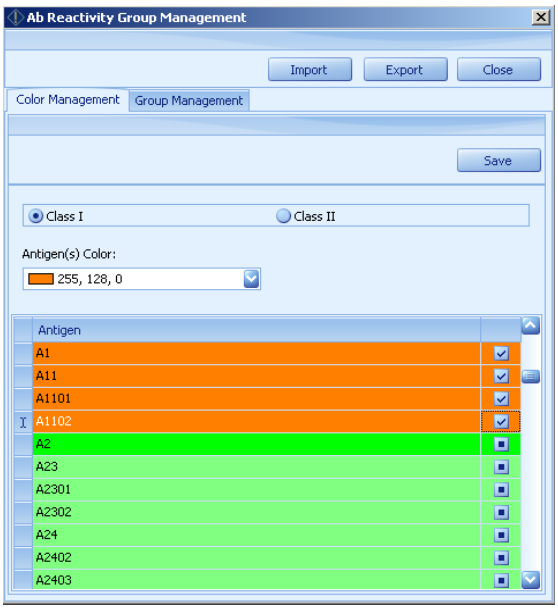
3) **Date Format Settings:** To change the date format that appears in the reports and user interfaces, the **Date Format Settings** may be changed in this tab. It is also necessary to select a date format used in the Luminex system which specifies the run date format in the output files generated by Luminex.

4) **Page Layouts:** This tab allows the user to restore a specific page lay-out to its default settings. This only needs to be performed if changes have been made to any of the layout of a particular assay. Select the layout and click restore.

5) **Report Settings**: This tab allows the user to choose paper size and address format. Settings will be applied to all reports.

Antibody Reactivity Groups

This menu item allows the user to create user defined antigen groups.



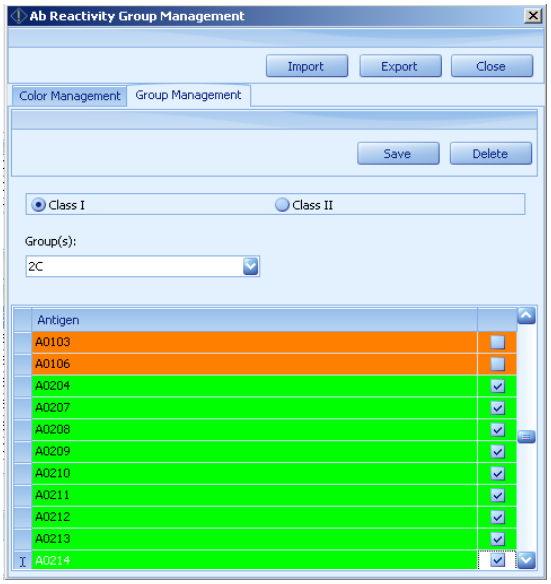
<u>To color code antigens:1) Under the Color Managment tab, choose either Class I or Class II.</u>

2) Choose a color from the *Antigen(s) Color* drop down menu.

3) Place a check mark next to all the antigens to be colored one color.

4) Click **Save**.

<u>To create or edit a group:</u>



1) Under the **Group Managment** tab, choose either **Class I or Class II**.

2) Choose an existing group from the drop down menu if edits are needed or choose **Add New**.

3) If creating a new group, type the name of the group in the box and click **OK**.

4) Place a check mark next to all antigens that need to be added to the newly created group or the group being edited.

5) Click **Save**.

<u>To Import/Export Group Data:</u>

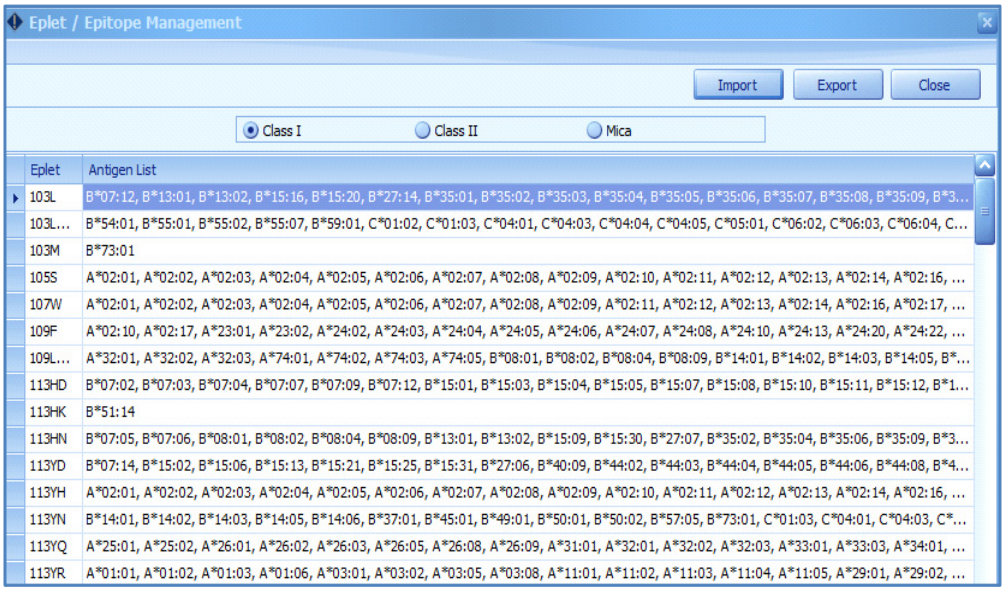
1) An already exisiting *.xml file* can be imported by clicking **Import.** This file is available on LIFECODES section of our website.

2) Once a category of groups is created, an .xml file can be exported by clicking **Export.**

Eplet/Epitope Management

This menu item allows the user to import or export Eplet information. The file containing the eplet information is a .csv file. Separate files must be imported for Class I, Class II, and MICA.

.



Tools

The *Tools Menu* gives the user access to management of certain properties in the software; such as display of lots, screen assignments to display, and management of both users and instruments.

Lot Availability

The *Lot Availability* window displays all templates and expiration dates imported into the database. The user has the option of which lots to make available by checking the box next to the lot under the Available column. If a lot is checked as *Available* then this lot can be used to import data and to create a batch.

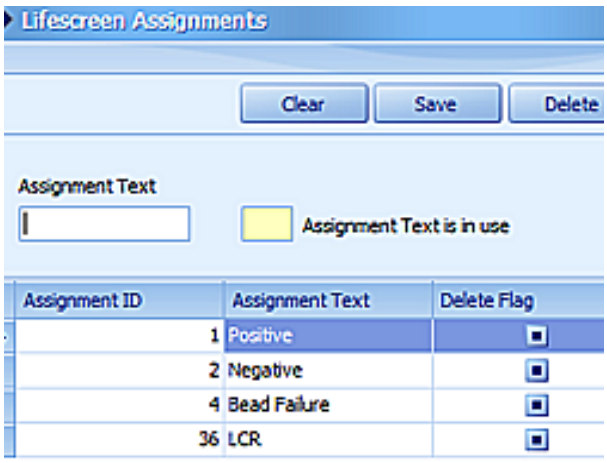
To search for a particular lot, type a portion of the lot ID in the *Lot Search* box.

Left-click any of the headers, *Lot ID, Expiration Date, Assay Name* to sort the column.

LifeScreen Deluxe Assignments

The *LifeScreen Deluxe Assignment Management* window allows the user to create assignments for use when analyzing LifeScreen Deluxe data. **Positive**, **Negative**, and **Failed** are automatically assigned to samples. High Background and **ND (Not Determined)** are default assignments but must be manually assigned when reviewing data. Other user defined assignments may be created or deleted in this management window.

Creating a LifeScreen Deluxe Assignment Text:

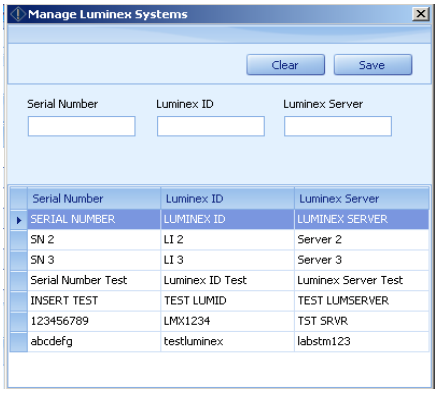


1) Type the desired text in the **Assignment Text** field; ex. Repeat.

2) Click **Save**.

3) The new assignment will now display in the drop down menu of Class I and II Assignments when reviewing LifeScreen Deluxe data. Once an *Assignment Text* is in use (highlighted), the text cannot be cleared or edited.

Manage Luminex Systems



The user may enter multiple Luminex instruments when in the **Manage Luminex Systems** window. *Serial Number, Luminex ID,* and *Luminex Server* should be entered and then saved.

When the software is first installed, it will search the network for existing Luminex databases. The Luminex instrument to which the batch is to be submitted may be selected from the dropdown list when in **Automated Batch Setup**. If the name of the computer to which the instrument is attached does not show up in the list, it may be typed in. *See "Chapter 3: Automated Batch Setup"*

Manage Users

The MATCH IT! software allows users to have unique log-ins. The login feature will prevent access to the software unless a user has been granted access during the activation process or if *Lab Supervisor* adds a user profile at a later date.

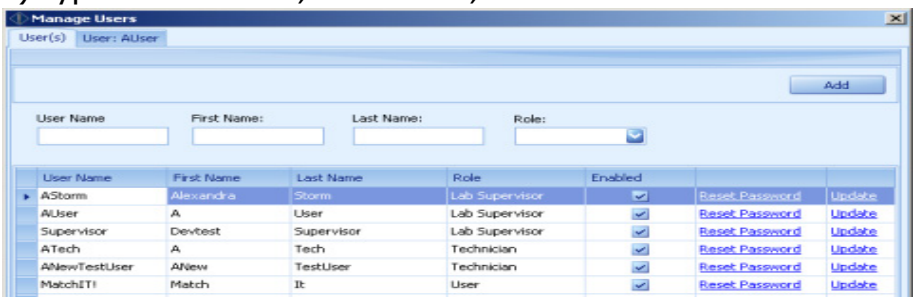
To create a user:

Note: The first time the software is installed, the login information is

username: supervisor

password: lifecodes

1) Type a *User Name, First Name,* and *Last Name.*



2) Choose the role: *Lab Supervisor, Technician,* or *User.*

A User: *Users* can only create other users. A *User* does not have the ability to save, complete or approve samples and is only in a read-only mode.

A Technician: *Technicians* can create other users and other *Technicians*. A *Technician* is able to make changes, add comments, save and complete samples.

A Lab Supervisor: *Lab Supervisors* can create all levels previously described plus other supervisors. A *Lab Supervisor* is able to perform all the roles of a *Technician* in addition to the ability to **Approve** samples and run Audit Reports.

3) Click **Add**.

4) Close the software.

To login or reset password:

1) Open the software. Type in the *user name* created in the steps above. The default password is **lifecodes**.

2) Go to the *User:(x)* tab and type the old password and then a any new password.

3) Click **Change Password**.

4) Clicking **Reset Password** will set password to **lifecodes.**

Available Assays

This menu item allows the user to choose what to display on the *Antibody* home tab. For example, if the user does not wish to display *LifeScreen* data, uncheck the *LifeScreen* choice found under *Antibody*.

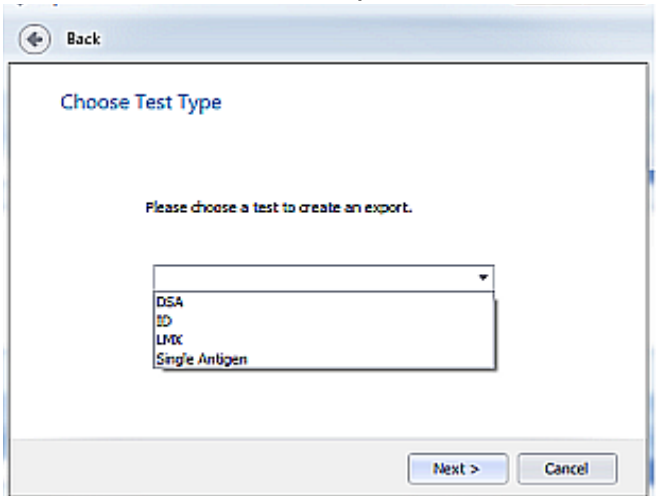
Exports/Reports

The *Exports/Reports Menu* item allows the user to export results and create reports.

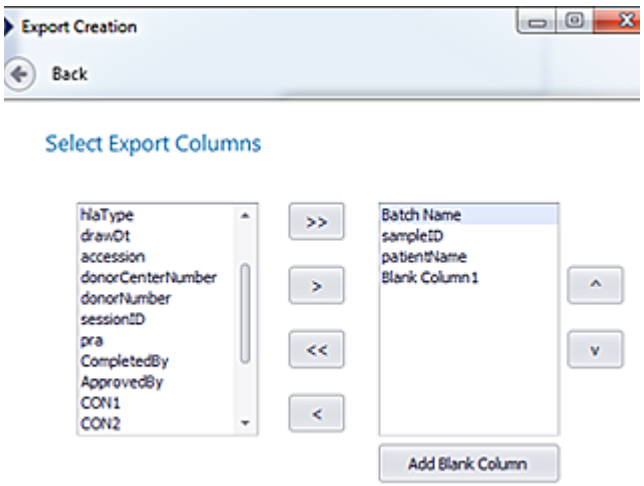
Export Design Wizard

The wizard will help the user to create a user defined export for all tests.

1) Choose a test to create an export.

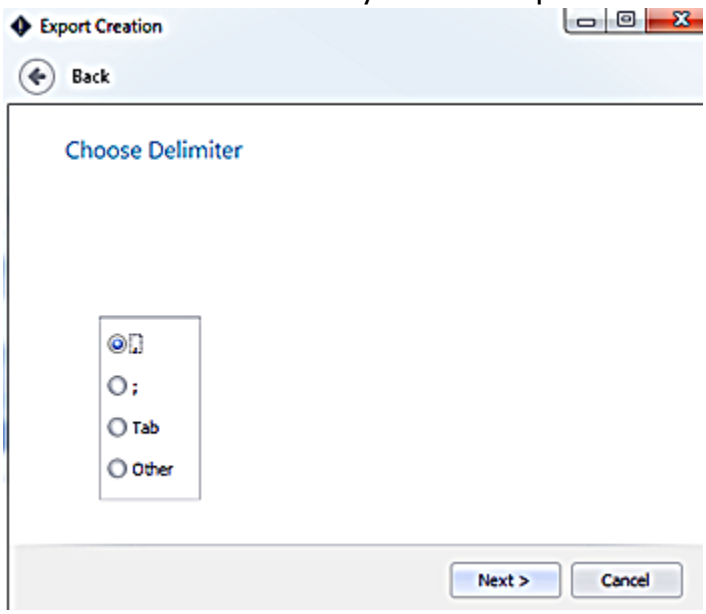


2) Customize the export columns to include in the final export.

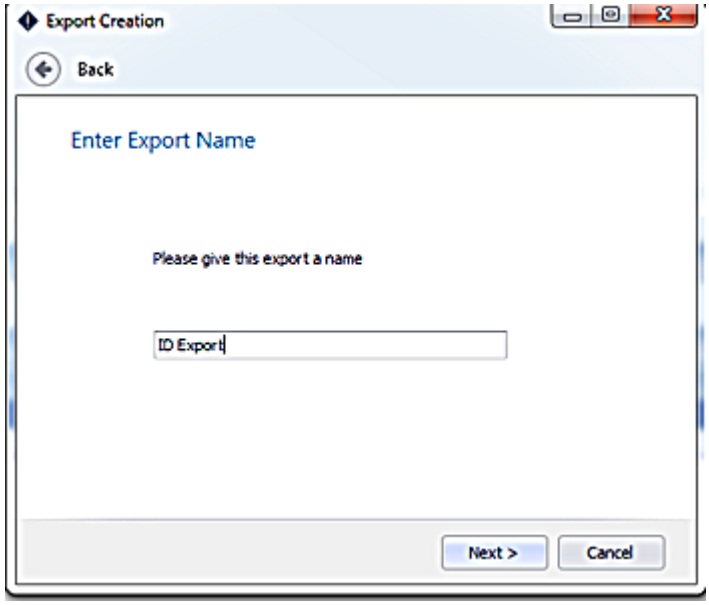


3) Columns can be moved once selected.

4) Choose a field delimiter for your final export.



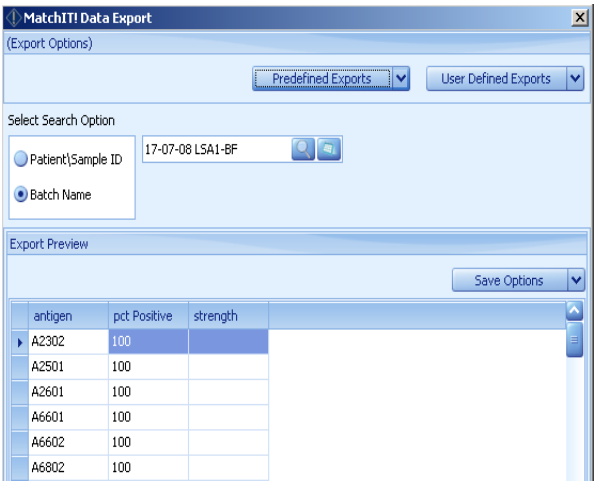
5) Name the final export.



Note: LSA-C3d** is not available in **Export Design Wizard.

Export Results

To export results:



1) Select a Search Option--*Sample ID* or *Batch Name*.

2) Type the full or partial *Sample ID* or *Batch Name* into the cell. Click the magnifying glass. The search results will appear.

3) Select the appropriate *Sample ID* or *Batch Name* from the search results.

4) Choose an *Export type*.

Predefined Exports:

Antibody Tail Export includes antigens with their % Postive score and Strength. Antigens display based on the % Positive setting in the Tail Parameters. For example if the % positive is set to 75%, only those antigens 75% and above will display in the export.

Antibody Tail ID includes PRA, Tail Antigens, and any user comments on individual samples.

LifeScreen Export includes all information from the LifeScreen data including individual sample information, raw data for each bead, run date, score, assignment and reviewer information.

User Defined Exports:

The user has the ability to create custom Exports to include all appropriate data. This is done through the Export Wizard as explained above.

5) If a *Sample Search* was performed, a list of *Batch IDs* will appear. Choose the appropriate batch. A preview of the *Export* will display.

If a *Batch Name Search* was performed, a list of *Batch IDs* will appear that contain all or part of the search text entered. Choose the appropriate batch. A preview of the *Export* will display.

6) Click the drop-down next to *Save Options* and choose the file type.

***Note: The Export button** on the homepage will display the same window*

Batch Reports

1) Click the magnifying glass to display a calendar.

2) Choose the date or range of dates when the batch was imported.

3) Batches will display on the left under *Batch*. Select the batch of choice. All samples within the batch will display under the *Sample* column.

4) Use the arrows to move the samples to the *Print (right)* column which will include them in the batch reporting.

5) Once all desired samples have been moved to the *Print (right)* column, choose the appropriate *Test* tab and *Reporting Option* for the test. Select **Send to Printer**, **Save to PDF**, **Save to Excel**, or **Save to RTF.** Multiple options may be chosen. If **Save to PDF**, **Save to Excel**, or **Save to RTF** is chosen browse to choose a **Save File Path**.

6) Click the **Print** icon. Dialog box will appear when printing is complete or reports have been generated.

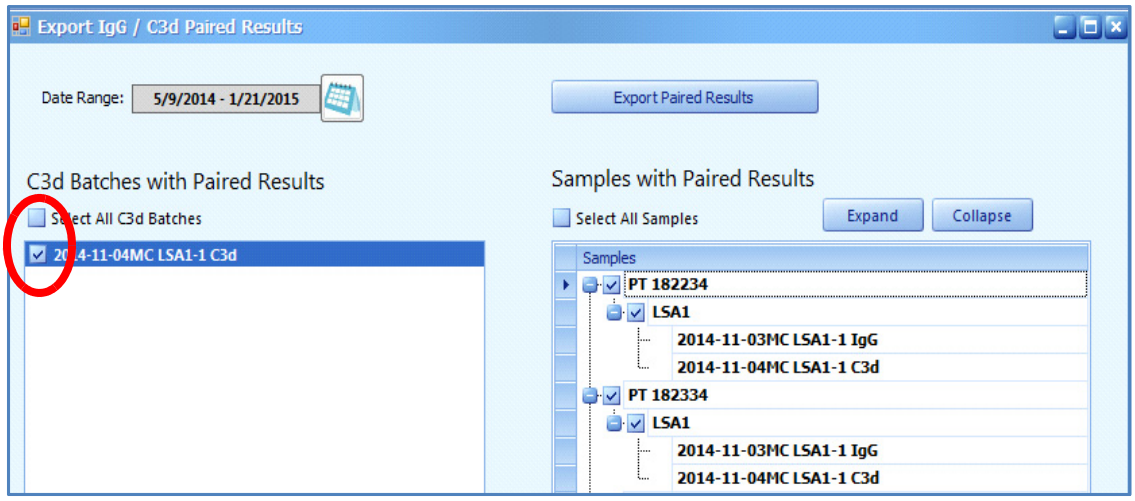
Note: The Antibody button *on the homepage will display the same window*

Export C3d Results

1) Click the Calendar Icon to select a run-date or range of run-dates to be displayed.

2) A list of C3d Batches with Paired results from the date range selected will appear in the left window.

3. The user can select individual batches or Select All C3d batches by clicking the appropriate box.

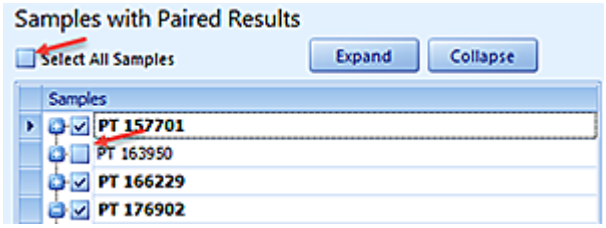


4) Samples paired through Patient View from the selected batch(es) will populate the window on the right and will be sorted by name.

a) The User can **Expand** or **Collapse** the batch information displayed for all samples sample by clicking the appropriate button.

b) The user can Expand or Collapse the batch information displayed for an individual sample by toggling the box next to the sample name

5) The user can select individual samples to export by marking the box next to the sample name. If all samples are required for export the user mark the **Select All Samples** box.



6)To Export the results, click the **Export Paired Results** Button. The user can then save the exported data to any desired location.

Note: *files exported will be csv format.*

CHAPTER 3: AUTOMATED BATCH SETUP

This chapter describes how to set up a batch. Detailed instructions are described including creating a sample list, choosing a Luminex connection, and then creating the entire batch for submission to the chosen Luminex.

Lot Information Import

Importing Template files into Luminex

Before creating a batch, the information necessary for identifying the appropriate beads to count must be imported into the Luminex software. The information is provided in lot-specific template files. Files with the extension .idt are designed for use with the Luminex IS 2.3 software. Files with the extension .lxt are designed for use with the Luminex xPonent software. Templates can be downloaded from the Immucor website.

To import an IDT file into Luminex IS 2.3

1) Go to **File>Import Template** found on the Luminex software home tab.

2) Navigate to the location, of the IDT file(s). Choose the appropriate file to be imported. Only one file may be chosen at a time.

3) A message will appear for each successful file import.

To import an LXT file into Luminex xPONENT

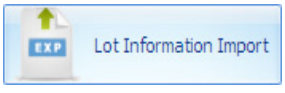
1) Select the **Protocols** Tab at the top of the Luminex xPONENT screen.

2) Click on the **Import** button on the bottom of the screen.

3) Navigate to the location of the LXT file(s). Choose the appropriate file to be imported. Only one file may be chosen at a time.

4) A message will appear for each successful file import.

Importing EDS files into MATCH IT!



Before creating a batch, the information necessary for analyzing data generated by the Luminex instrument must be imported. The information is provided in lot-specific EDS files. To import an EDS file:

1) Click **Lot Information Import** found on the *Home Screen*. The *Open* dialog box will appear.

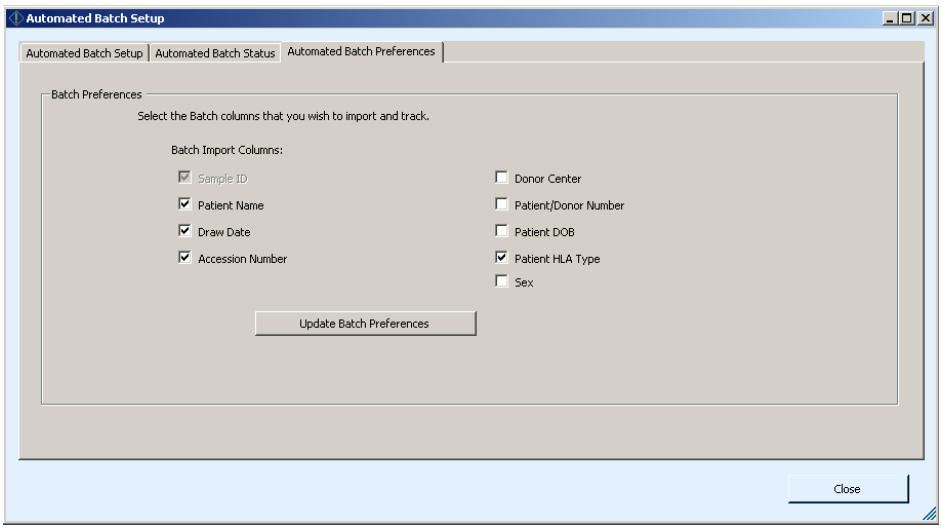
2) Navigate to the location of the EDS file(s). Select all appropriate files that need to be imported. More than one may be selected at one time by pressing Ctrl + left mouse button.

3) Click **Open**. A message will appear when all selected files have imported successfully.

Automated Batch Setup

Setting Automated Batch Preferences

This tab customizes the information to be either entered manually or imported from a sample list. To customize which import columns to include in a batch**:**



1) Click **Automated Batch Setup** on the *Home Screen*.

2) Go to the **Automated Batch Preferences** tab.

3) Place a check in the box next to each item to be included as an import column.

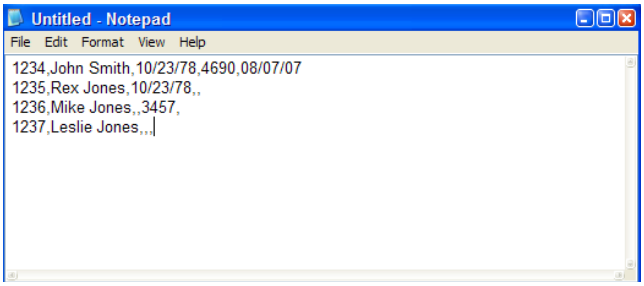
4) Save by clicking **Update Batch Preferences**. Once *Batch Import Columns* are selected, they will appear as columns under the **Automated Batch Setup** tab.

Creating a Sample List (optional)

A sample list is a file containing a comma separated list of the data selected on the **Automated Batch Preferences** tab. As a minimum, the *Sample ID* is present in each list. All other fields are optional. To create a *Sample List*:

1) Open a blank *Notepad* document.

2) Enter all column information. Each piece of information must be delimited by a comma regardless of whether the information is present or not.



Do not hit return after the last sample is entered.

3) Save the file

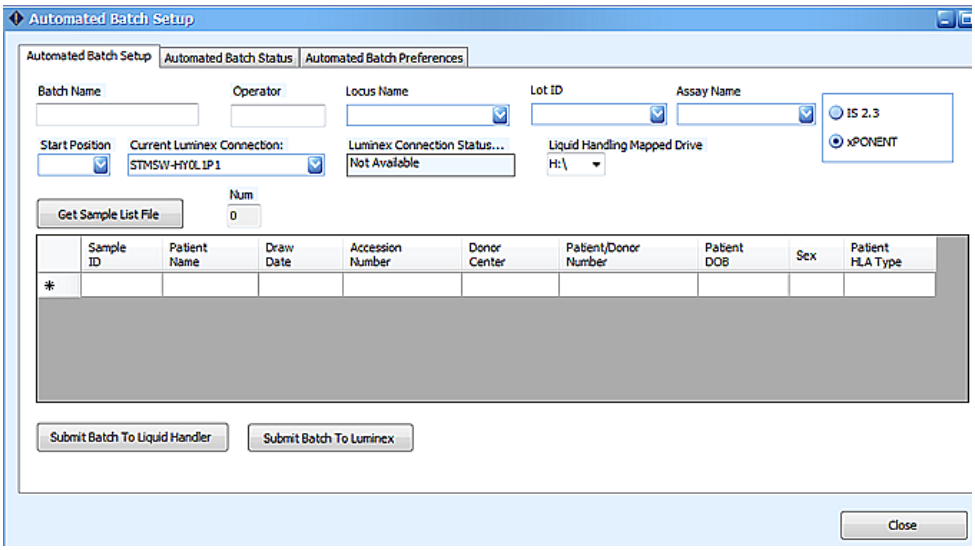
Note: *Enter the Sample HLA Type in the same serological format used in the LIFECODES worksheets. In order for antigens to be excluded, they must match an antigen listed on the product worksheet. For example, if A1 is entered, it will be excluded. Entries such as A01, A01/02, etc. will not be excluded. For Single Antigen, the allele must be entered such as A*01:01. This allows those antigens to be excluded during the analysis of the HLA antibody. No commas should be entered between antigens. Draw Date must be in the format selected in Preferences*

Warning: *When creating patient lists for LSA-C3d, the name used for the Negative Control sample MUST match exactly the name listed under C3d settings. If this condition is not met, auto-import of this batch will fail.*

Creating a Batch

In order to create an automated batch, the EDS file for the particular product and lot must be imported into the LIFECODES MATCH IT! software *See "Importing EDS files into MATCH IT!"* and the correct Luminex Template must be imported into the Luminex Software *See "Importing Template files*

into Luminex". To create a batch:



1) Click **Automated Batch Setup** on the *Home Screen.*

2) Go to the **Automated Batch Setup** tab.

3) Select IS 2.3 or xPONENT.

4) Enter a *Batch Name*.

Note: Session names cannot be reused and cannot exceed 30 characters including spaces. Session names cannot contain apostrophes or commas and will not be imported and analyzed until the panel name is changed.

5) Enter user initials in *Operator*.

6) Choose a *Test Type*: LifeScreen Deluxe, Class I ID, etc.

7) Choose the appropriate *Lot ID*. *Assay Name* should automatically populate with the Lot ID.

8) Enter a *Start Position* (well location on plate).

9) Choose the Luminex instrument to which the batch is to be submitted from the dropdown list under *Current Luminex Connection* and verify that *Luminex Connection Status* is *Available*. If the name of the computer to which the instrument is attached does not display in the list, it may be typed in.

10) To load a pre-saved *Sample List*, click **Get Sample List File**. The user may type directly into the columns as well.

11) To submit the batch to Luminex, click **Submit Batch to Luminex**. In order for the batch to be submitted, the Luminex Template for the particular product lot must be present in the Luminex database as described above.

At this point, the batch will be ready for selection in the Luminex Software.

12) To submit a batch to an Automated Liquid Handler, choose the Liquid Handling Mapped Drive and then click **Submit Batch to Liquid Handler**. A dialog box will appear.

If the liquid handler will be submitting the Luminex run to the Luminex Instrument, the user must select **Yes**. After selecting **Yes** or **No**, a message will indicate that the batch was submitted successfully.

This process generates two files—a configuration file and a sample list file that are used by the liquid handler to submit a batch to the Luminex Instrument.

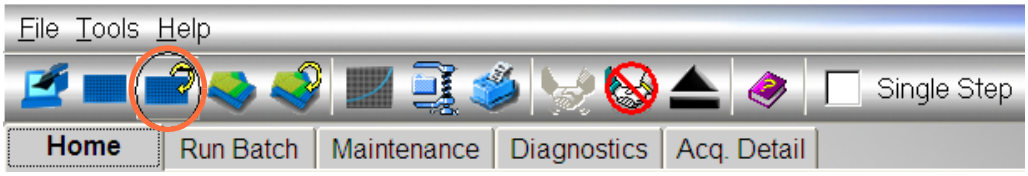
NOTE: Specialized Luminex Templates have been developed by LIFECODES for use with liquid handlers. These templates must be used in order for the integration of the Luminex and liquid handler to function properly.

Running a Batch in Luminex

Running a Single Batch in Luminex IS 2.3

Once an Automated Batch is created and submitted to Luminex the user must give the command for the Luminex software to acquire the samples within a batch.

1) On the tool bar at the top of the Luminex IS 2.3 Software, click **Open Batch**.



2) Any batches that have not been acquired in the Luminex IS software will be listed here. Highlight the batch to be acquired and click **Select.**

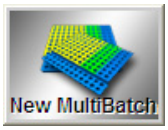
3) Verify the plate is a direct representation of the *Run Batch* screen in the Luminex software.

4) To acquire the samples, click **Start Plate** once the sample tray has been placed into the XY Platform of the Luminex system.

Note: It is not possible to change positions when opening a single batch. The correct position needs to be selected when Creating the Automated Batch.

Running a Multi-Batch in Luminex IS 2.3

Once an Automated Batch is created and submitted to Luminex the user must give the command for the Luminex software to acquire the samples within a multi-batch.



1) Click **Create Multi Batch** found on the homepage of the Luminex IS software.

2) Click the **Add Batch** icon in the top left hand corner of the screen. Any batches that have not been acquired in the Luminex IS software will be listed here.

3) Highlight the batch to be added to the multi-batch and click **Select.**

3) Repeat steps 1 and 2 until all desired batches have been added to the multi-batch.

4) Verify the plate is a direct representation of the *Run Batch* screen in the Luminex software.

5) Name the multi-batch and add the user's initials. **Click Save.** The multi-batch will automatically load, but could be saved for a future date if necessary by choosing **Open Multi-Batch**.

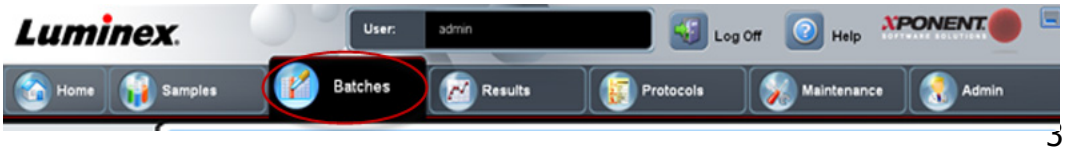
6) To acquire the samples, click **Start Plate** once the sample tray has been placed into the XY Platform of the Luminex system.

Note: It is possible to change positions when creating a multi- batch. As the batches are added, drag the first sample of the batch to the desired location.

Running a Single Batch in Luminex xPONENT

1) Open the xPONENT software and sign in as *admin.*

2) Select the **Batches** Tab at the top of the screen.



3) All batches that have not been acquired will be listed under **Pending Batches**

4) Select a batch by clicking on it. To Review batch contents select **Plate Layout**. To run click the **Run** button at the bottom of the screen.

Running a Multibatch in Luminex xPonent

1) In the batches tab, select Create a New Multi-Batch

2) Select the first batch to be included and click **OK.**

3) To add another batch, click on the well where that corresponds with the first sample in the batch and select the **Add** button at the bottom of the screen. To delete batches select the batch and click **Remove**.

4) Repeat step 3 until all desired batches have been added.

5) Verify that the plate is a direct representation of the Multi-Batch screen in the software.

6) Click **Run** to process immediately or **Save** to process at a later time.

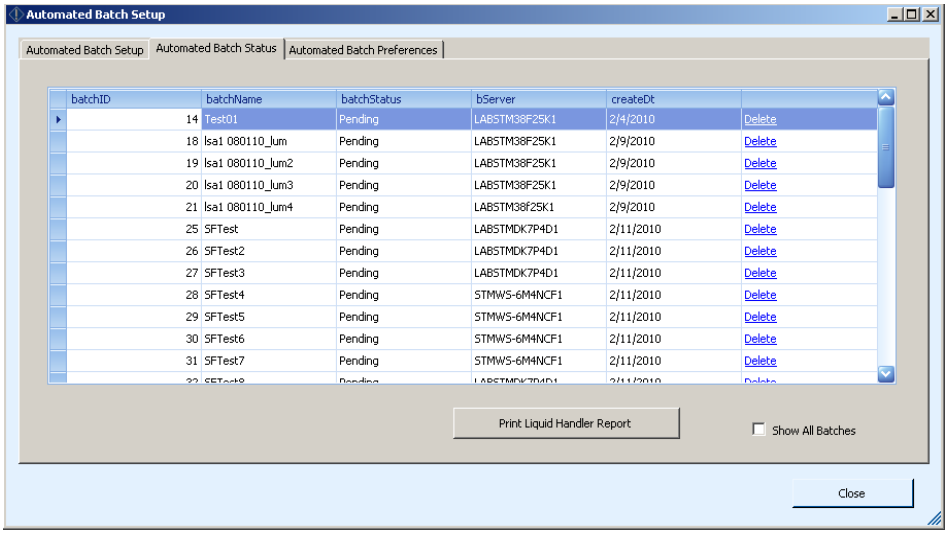
Note: The first batch in a multi-batch will, by default be added to well A1. If this is not the location of the first batch in your multi-batch, Add the second batch to the correct location according to the instructions above then Remove the first batch. You can now add this batch back to the correct location following the steps above.

Batch Status

The status of a batch can be verified in the MATCH IT! software.

1) Click **Automated Batch Setup** from the homepage.

2) Choose the **Automated Batch Status** tab.


Automated Batch Setup
Automated Batch Setup
Automated Batch Status
Automated Batch Preferences
batchID batchName batchStatus bServer createDt
14 Test01 Pending LABSTM38F25K1 2/4/2010 Delete
18 lsa1 080110_lum Pending LABSTM38F25K1 2/9/2010 Delete
19 lsa1 080110_lum2 Pending LABSTM38F25K1 2/9/2010 Delete
20 lsa1 080110_lum3 Pending LABSTM38F25K1 2/9/2010 Delete
21 lsa1 080110_lum4 Pending LABSTM38F25K1 2/9/2010 Delete
25 SFTest Pending LABSTMDK7P4D1 2/11/2010 Delete
26 SFTest2 Pending LABSTMDK7P4D1 2/11/2010 Delete
27 SFTest3 Pending LABSTMDK7P4D1 2/11/2010 Delete
28 SFTest4 Pending STMWS-6M4NCF1 2/11/2010 Delete
29 SFTest5 Pending STMWS-6M4NCF1 2/11/2010 Delete
30 SFTest6 Pending STMWS-6M4NCF1 2/11/2010 Delete
31 SFTest7 Pending STMWS-6M4NCF1 2/11/2010 Delete
Print Liquid Handler Report
Show All Batches
Close

3) Pending batches (those not yet acquired in the Luminex IS 2.3 or xPONENT software) will be displayed. To see completed batches as well, check *Show All Batches.* A pending batch may be deleted by clicking **Delete**.

Note: Deleting completed batches from the Batch Status will prevent them from appearing in the home-screen. Only Pending batches that will not be run should be deleted from this window.

4)Upon completion of a Batch acquisition in Luminex, the batch will be automatically imported into Matchit! It is neccessary to refresh the home-screen to view newly imported automated batches.

CHAPTER 4: LIFESCREEN DELUXE ANALYSIS

This chapter contains information on the tools available to analyze LifeScreen Deluxe results (LifeScreen).

Importing LifeScreen Results into MATCH IT!

If an Automated Batch was not created and data needs to be manually imported into the software, the appropriate EDS file must first be imported followed by the csv file.

Importing EDS files

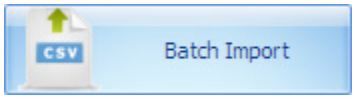
Before importing LifeScreen data, the information necessary for analyzing the data generated by the Luminex instrument must be imported. The information is provided in lot-specific EDS files.

1) Click **Lot Information Import** found on the Home tab of MATCH IT!. The Open dialog box will appear.

2) Navigate to the location, e.g., desktop, of the EDS file(s). Select all appropriate files that need to be imported. Use Ctrl + left mouse button to select more than one EDS file at one time.

3) Click **Open**. A message when all lots have successfully imported.

Manually Importing CSV Files



1) Click **Batch Import** from the homepage. This will open the *Open* dialog box.

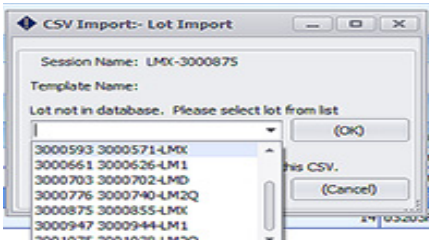
2) Navigate to the location of the CSV file(s). If importing from the computer connected to the Luminex, CSV files can be found in C:\My Batches\Output on IS 2.3 systems and at C:\ProgramData\Luminex\xPONENT31\Output on xPonent systems.

3) Select all CSV files to be imported. Use Ctrl + left mouse button to select more than one CSV file at one time.

4) When the file is selected, the analysis is done automatically during the import process. Once the csv file has been imported, it will appear on the Antibody Home tab under *LifeScreen*.

Note: *A* ***CSV Import: Lot Import*** *may appear after selecting a csv file. This can be due to:1) the appropriate EDS file not being imported, 2) the*

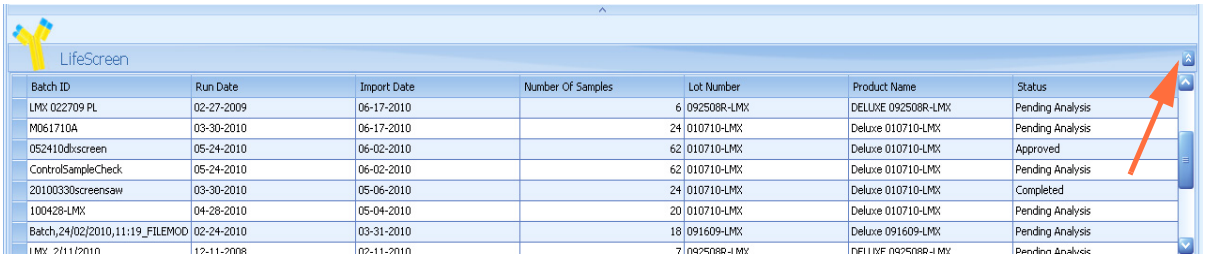
EDS file not being available *See "Lot Availability"* *, or 3) the lot number not being indicated on the CSV file.*



Opening a Batch

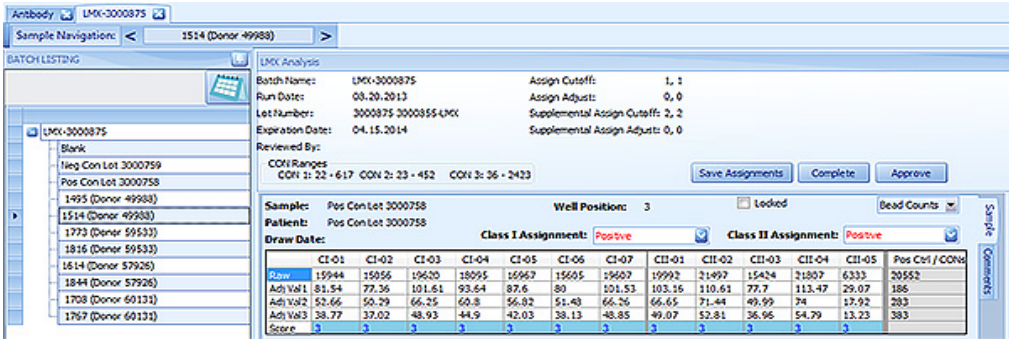
Direct Selection

1) Click the arrow to first expand the *LifeScreen* section.


LifeScreen
Batch ID | Run Date | Import Date | Number Of Samples | Lot Number | Product Name | Status
LMX 022709 PL | 02-27-2009 | 06-17-2010 | 6 | 092508R-LMX | DELUXE 092508R-LMX | Pending Analysis
M061710A | 03-30-2010 | 06-17-2010 | 24 | 010710-LMX | Deluxe 010710-LMX | Pending Analysis
052410dlxscreen | 05-24-2010 | 06-02-2010 | 62 | 010710-LMX | Deluxe 010710-LMX | Approved
ControlSampleCheck | 05-24-2010 | 06-02-2010 | 62 | 010710-LMX | Deluxe 010710-LMX | Pending Analysis
20100330screensaw | 03-30-2010 | 05-06-2010 | 24 | 010710-LMX | Deluxe 010710-LMX | Completed
100428-LMX | 04-28-2010 | 05-04-2010 | 20 | 010710-LMX | Deluxe 010710-LMX | Pending Analysis
Batch,24/02/2010,11:19_FILEMOD | 02-24-2010 | 03-31-2010 | 18 | 091609-LMX | Deluxe 091609-LMX | Pending Analysis

2) Double click the batch name found on the Antibody Home tab under *LifeScreen*

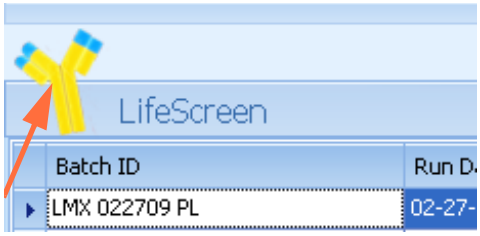
3) The batch results are displayed in an *LMXAnalysis* tab. All sample results appear in the middle section of the tab. Individual sample IDs within the selected panel are listed in the left section of the tab under the batch name.



Date Range Selection

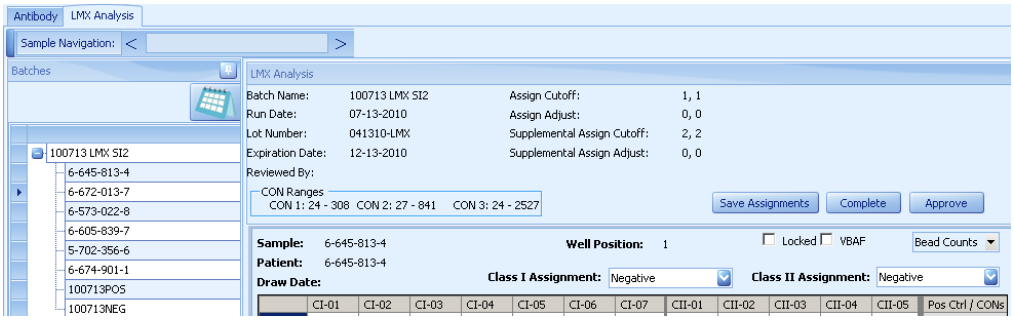
Rather than selecting an individual batch, a range of dates can be selected, which will result in all batches run in that range being selected.

1) Right click the antibody symbol as shown below.



2) A pair of calendars with a start and end date will open. Select the desired range and click **OK**.

3) The batch results are displayed in an *LifeScreen Analysis* tab. All sample results for the highlighted batch appear in the middle section of the tab. Individual sample IDs within the selected panel are listed in the left section of the tab under the batch name.



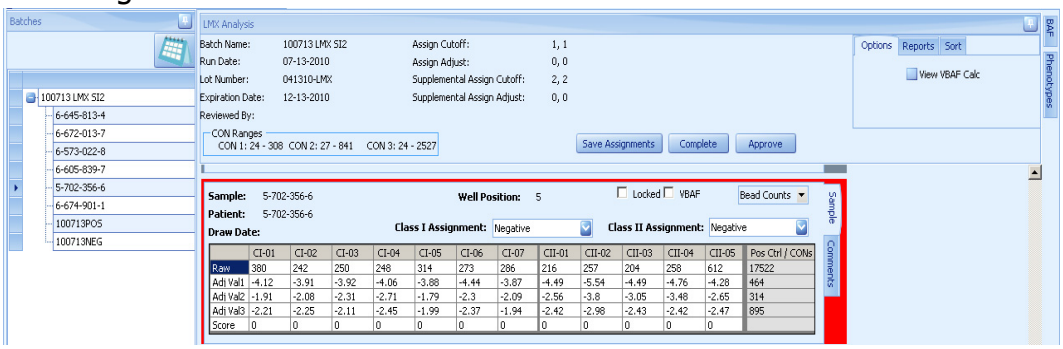
Viewing and Changing the Results of a Batch

Scrolling through a Batch

If all of the data for the batch does not appear on the screen, the scroll bar can be used to move among the different samples.

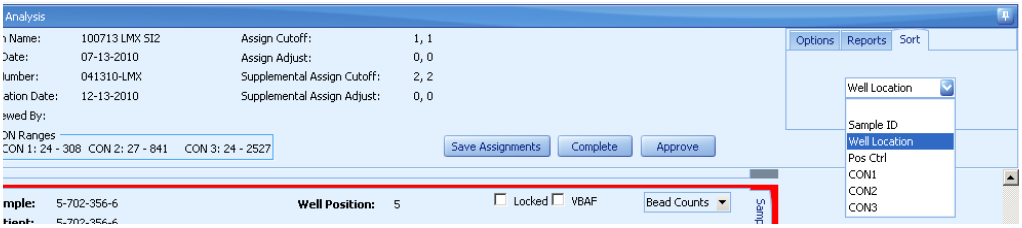
Navigating to a Particular Sample

To view a particular sample in the batch, left click the sample name in the left hand pane. The software will jump to this sample and it will be highlighted in red.


Batches
LMX Analysis
100713 LMX SI2
6-645-813-4
6-672-013-7
6-573-022-8
6-605-839-7
5-702-356-6
6-674-901-1
100713POS
100713NEG
Batch Name: 100713 LMX SI2
Run Date: 07-13-2010
Lot Number: 041310-LMX
Expiration Date: 12-13-2010
Reviewed By:
Assign Cutoff: 1, 1
Assign Adjust: 0, 0
Supplemental Assign Cutoff: 2, 2
Supplemental Assign Adjust: 0, 0
Options
Reports
Sort
View VBAF Calc
CON Ranges
CON 1: 24 - 308 CON 2: 27 - 841 CON 3: 24 - 2527
Save Assignments
Complete
Approve
Sample: 5-702-356-6
Patient: 5-702-356-6
Draw Date:
Well Position: 5
Locked
VBAF
Bead Counts
Class I Assignment: Negative
Class II Assignment: Negative
CI-01 CI-02 CI-03 CI-04 CI-05 CI-06 CI-07 CII-01 CII-02 CII-03 CII-04 CII-05 Pos Ctrl / CONs
Raw 380 242 250 248 314 273 286 216 257 204 258 612 17522
Adj Val1 -4.12 -3.91 -3.92 -4.06 -3.88 -4.44 -3.87 -4.49 -5.54 -4.49 -4.76 -4.28 464
Adj Val2 -1.91 -2.08 -2.31 -2.71 -1.79 -2.3 -2.09 -2.56 -3.8 -3.05 -3.48 -2.65 314
Adj Val3 -2.21 -2.25 -2.11 -2.45 -1.99 -2.37 -1.94 -2.42 -2.98 -2.43 -2.42 -2.47 895
Score 0 0 0 0 0 0 0 0 0 0 0 0
Sample
Comments

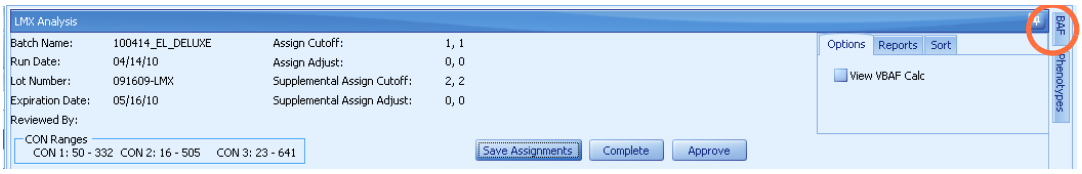
Changing the Sort Order

The samples within a batch are loaded in order of their location in the batch. By selecting the sort tab located in the upper right, the results can be ordered by *Sample ID*, *Well Location* (default), *CON1, CON2, CON3* or *Pos Ctrl Bead*.



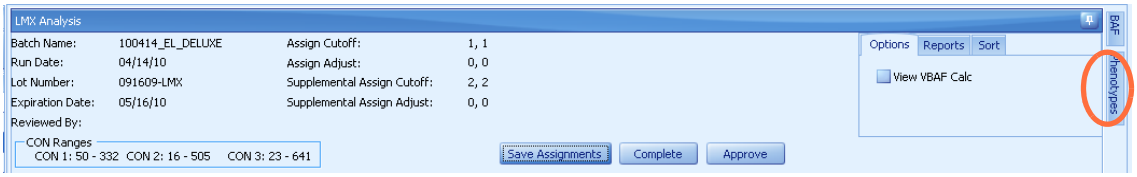
Displaying BAF Values

To display BAF values, click *BAF* on the right tab.



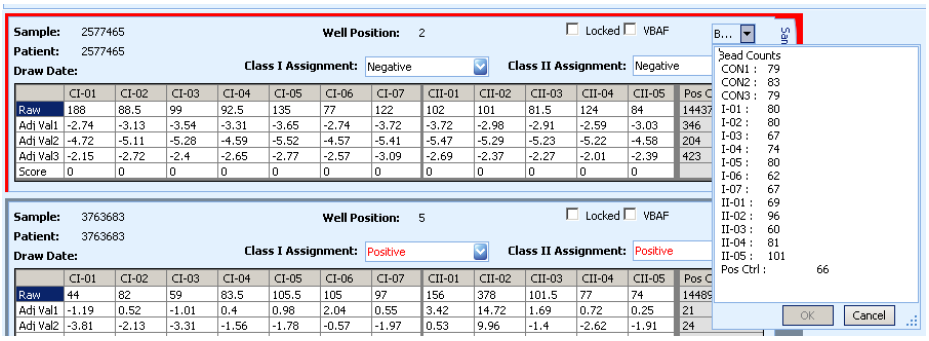
Displaying Phenotypes

To display the list of antigens on the beads, click *Phenotypes*.



Displaying Bead Counts

To display the bead counts for a sample, click the down arrow next to *Bead* in the sample header.



Assignments, Displayed Values and Calculations

Bead Assignment

To determine the adjusted value for a bead, the individual bead MFI is divided by the MFI for each Negative Control Bead (CON1, CON2, CON3). From these quotients, the Background Adjustment Factor (BAF) for the appropriate bead/CON combination is subtracted. The BAF is a pre-determined MFI ratio for each bead/CON combination to compensate for background noise due to bead variation. See the lot-specific Recording Sheet provided with the kit for BAF values.

(Individual Bead MFI ÷ CON1 MFI) - BAF = Adjusted Ratio 1

(Individual Bead MFI ÷ CON2 MFI) - BAF = Adjusted Ratio 2

(Individual Bead MFI ÷ CON3 MFI) - BAF = Adjusted Ratio 3

- For I-01 and II-01, a positive value for any one of the calculations indicates a positive bead reaction.
- For all remaining beads, a positive value for any two of the calculations indicates a positive bead reaction.
- A negative value for all three calculations indicates a negative bead reaction.
- The *Score* shown in the *Results Table* is the number of above calculations that exceed the *Assign Adjust* value. By default, the *Assign Adjust* values are set to zero. *See "Preferences"*

Class Assignment

- A sample is considered to be positive for class I HLA-specific antibodies if at least one of the seven (7) class I HLA beads is positive.
- A sample is considered to be positive for class II HLA-specific antibodies if at least one of the five (5) class II HLA beads is positive.
- A sample is considered to be negative for HLA-specific IgG antibodies if all the HLA beads are found to be negative.

Batch Failures

Bead Count Failure

- If a sample fails to meet the minimum bead count for a Class I or Class II bead, the Class I or Class II result, respectively, will be reported as Bead Failure. To override the failure, review the bead count and then choose the appropriate assignment from the drop-down menu.

•If a CON bead fails to meet the minimum bead count, the software will report Bead Failure for both Class I and Class II.

Positive or Negative Control Failure (when using a liquid handler)

The software can be set so that the results for the entire batch are tied to the performance of the Positive and Negative control when a liquid handler is used. All samples will be listed as failed if either the Positive or Negative Control samples fail.

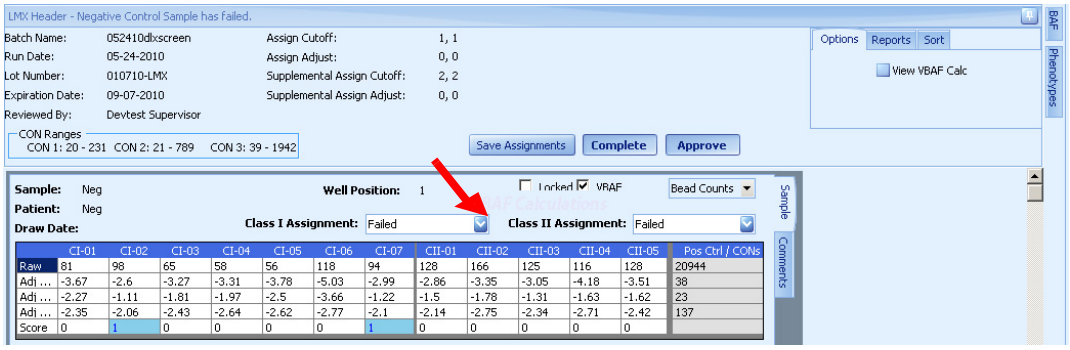
•A Negative Control is considered as failed if any bead fails to meet the minimum bead count, or if the Negative Control has a positive assignment for Class I or Class II.

•A Positive Control is considered as failed if any bead fails to meet the minimum bead count, or if either of the Class I or Class II assignment is negative.

•The source of the failure is listed in the *LifeScreen Header*. Bead failures will only be listed within the panel not in the header. The feature that ties the performance of the batch to the performance of the negative and positive controls can be enabled or disabled in *Lab Settings* feature. *See "Preferences"*

Overriding an Assignment

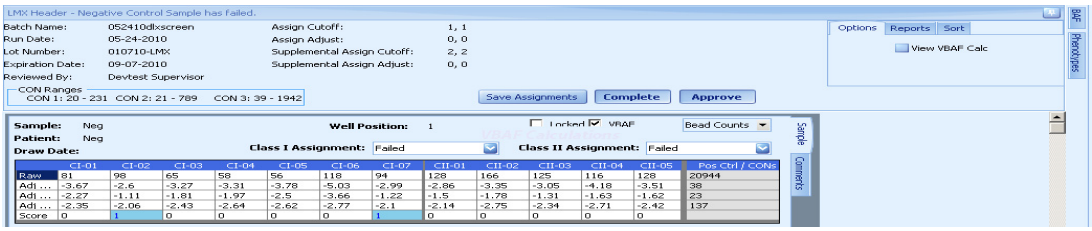
While the software performs analysis according to the product insert, all results should be reviewed. During this review process, an assignment can be changed manually by clicking the arrow on the right side of the text box and selecting one of the choices that appears.


LMX Header - Negative Control Sample has failed.
Batch Name: 052410dlxscreen
Run Date: 05-24-2010
Lot Number: 010710-LMX
Expiration Date: 09-07-2010
Reviewed By: Devtest Supervisor
Assign Cutoff: 1, 1
Assign Adjust: 0, 0
Supplemental Assign Cutoff: 2, 2
Supplemental Assign Adjust: 0, 0
Options
Reports
Sort
View VBAF Calc
CON Ranges
CON 1: 20 - 231 CON 2: 21 - 789 CON 3: 39 - 1942
Save Assignments
Complete
Approve
Sample: Neg
Patient: Neg
Draw Date:
Well Position: 1
Locked
VBAF
Bead Counts
Class I Assignment: Failed
Class II Assignment: Failed
CI-01 CI-02 CI-03 CI-04 CI-05 CI-06 CI-07 CII-01 CII-02 CII-03 CII-04 CII-05 Pos Ctrl / CONs
Raw 81 98 65 58 56 118 94 128 166 125 116 128 20944
Adj ... -3.67 -2.6 -3.27 -3.31 -3.78 -5.03 -2.99 -2.86 -3.35 -3.05 -4.18 -3.51 38
Adj ... -2.27 -1.11 -1.81 -1.97 -2.5 -3.66 -1.22 -1.5 -1.78 -1.31 -1.63 -1.62 23
Adj ... -2.35 -2.06 -2.43 -2.64 -2.62 -2.77 -2.1 -2.14 -2.75 -2.34 -2.71 -2.42 137
Score 0 1 0 0 0 0 1 0 0 0 0 0
BAF
Phenotypes
Sample
Comments

Overriding Default Parameters

The default parameters *(Assign Adjust and Assign Cutoff)* should only be altered by personnel knowledgeable in the field of HLA Antibody Analysis. Changing these values will result in altered specificity and sensitivity of the assay. *See "Antibody Parameters:"*

Optional VBAF Analysis


LMX Header - Negative Control Sample has failed.
Batch Name: 052410dkscreen
Run Date: 05-24-2010
Lot Number: 010710-LMX
Expiration Date: 09-07-2010
Reviewed By: Devtest Supervisor
Assign Cutoff: 1, 1
Assign Adjust: 0, 0
Supplemental Assign Cutoff: 2, 2
Supplemental Assign Adjust: 0, 0
Options
Reports
Sort
View VBAF Calc
CON Ranges
CON 1: 20 - 231 CON 2: 21 - 789 CON 3: 39 - 1942
Save Assignments
Complete
Approve
Sample: Neg
Patient: Neg
Draw Date:
Well Position: 1
Locked
VBAF
Bead Counts
Class I Assignment: Failed
Class II Assignment: Failed
CI-01 CI-02 CI-03 CI-04 CI-05 CI-06 CI-07 CII-01 CII-02 CII-03 CII-04 CII-05 Pos Ctrl / CONs
Raw 81 98 65 58 56 118 94 128 166 125 116 128 20944
Adj ... -3.67 -2.6 -3.27 -3.31 -3.78 -5.03 -2.99 -2.86 -3.35 -3.05 -4.18 -3.51 38
Adj ... -2.27 -1.11 -1.81 -1.97 -2.5 -3.66 -1.22 -1.5 -1.78 -1.31 -1.63 -1.62 23
Adj ... -2.35 -2.06 -2.43 -2.64 -2.62 -2.77 -2.1 -2.14 -2.75 -2.34 -2.71 -2.42 137
Score 0 1 0 0 0 0 1 0 0 0 0 0
Sample
Comments
BAF
Parameters

Applying VBAF to an Entire Batch

To apply the VBAF calculation to the entire batch, select *View VBAF Calc* from the *Options* tab.

Applying VBAF to a Single Sample

To apply the VBAF calculation to a single sample, select the *VBAF Calc* checkbox in the header of the individual samples.

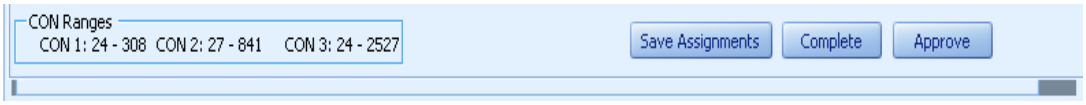
Approving the Results of the Analysis

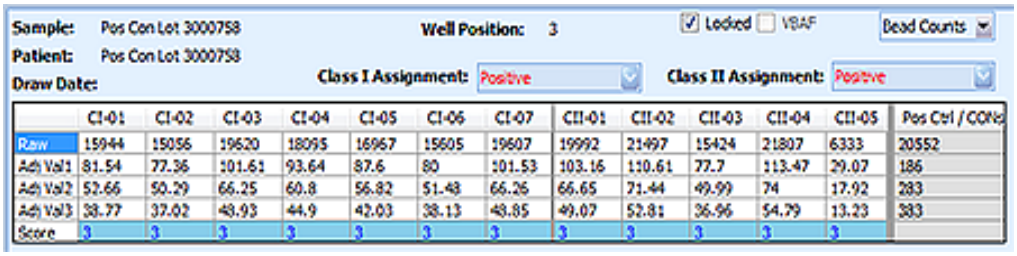
Saving, Completing, and Approving an Assignment

The **Save Assignments** button saves any assignment edits that have been made. Changes can be made and re-saved.

The **Complete** button locks all the samples in the batch and signifies all samples have been analyzed and are ready for sign-off. When a batch has been completed and locked, only a *Lab Technician* or *Lab Supervisor* may unlock the samples by clicking **Complete** again. Only a *Lab Supervisor* can unlock a single sample by clicking the **Locked** box. Completing the results lists the batch as *Completed* on the home page.

The **Approve** button signifies that analysis of the samples is finished. Only a *Lab Supervisor* can approve or unapprove a batch. To unapprove, click **Approve** again. Lab Supervisors can also unlock individual samples by clicking the **Locked** box. Approving the results lists the batch as *Approved* on the home page.





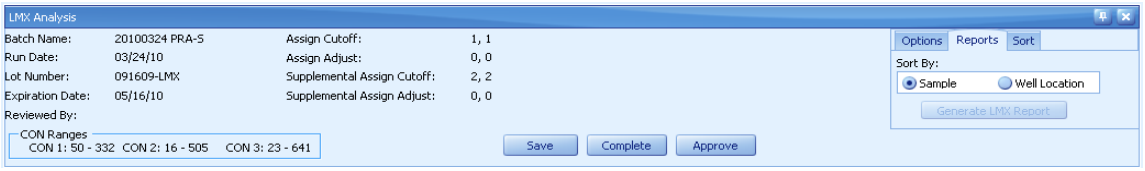
Reports

Printing Standard Report

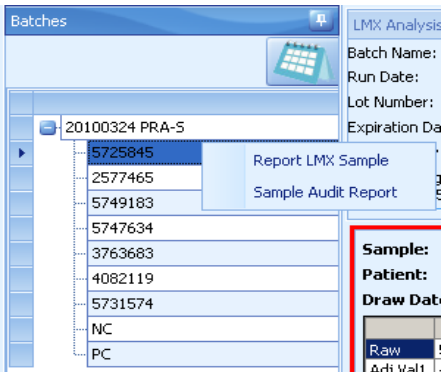
1) Once the results have been approved, a standard report may be run. The report for the batch can be ordered by sample or well location.

2) The report is created by clicking the **Generate LMX Report** button.

3) Once a report appears on the screen, click the **Print** icon in the upper toolbar.



Printing an Individual Sample Report or Audit Report



1) Select the sample ID in the *Batch Listing* pane.

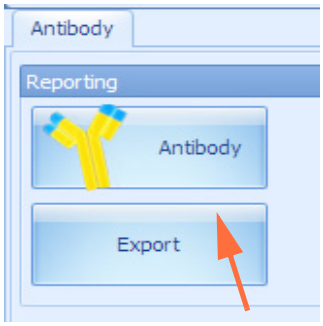
2) Right click the sample ID to access the report options: *Report LifeScreen Sample* or *Sample Audit Report.* A *Sample Audit Report* will only be generated if changes to the sample have been made. If no changes then no report will appear.

3) Once a report appears on the screen, click the **Print** icon in the upper toolbar.

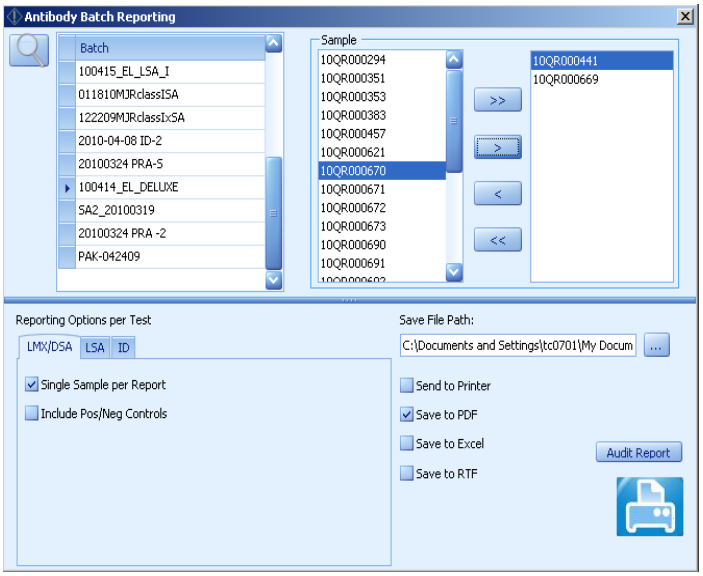
Batch Reporting

1) Go to the *Home Antibody* tab.

2) Click the *Antibody* icon.



3) Click the magnifying glass to display a calendar.



4) Choose the date or range of dates of when the batch was imported.

5) Batches will display in the *Batch* column. Double click the batch of choice. All samples within the batch will display in the *Sample* column.

6) Use the arrows to move the samples to the *Print (right)* column which will include them in the batch report.

7) If individual reports of the samples moved to the *Print (right)* column are preferred, choose the LMX/DSA tab under **Reporting Options per Test** and check *Single Sample per Report*. There is then the option to *Include Pos/Neg Controls*.

8) Select desired **Printing Option**: *Send to Printer, Save to PDF, Save to Excel,* or *Save to RTF*. Multiple options may be chosen. If *Save to PDF, Save to Excel*, or *Save to RTF* is chosen choose a *Save File Path*.

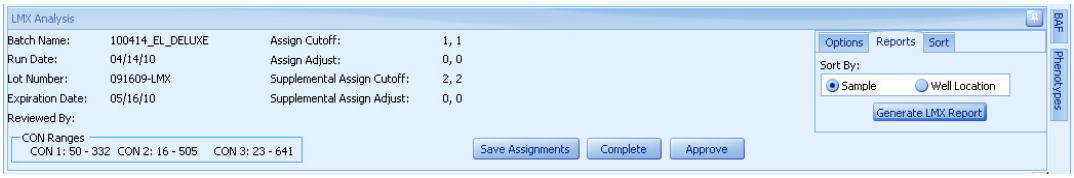
9) Click the *Print icon*. Either one report containing all chosen samples will be generated or individual reports for each chosen sample will be generated.

10) If an *Audit Report* is desired, click **Audit Report**. This report is only available in pdf format.

Exporting Reports

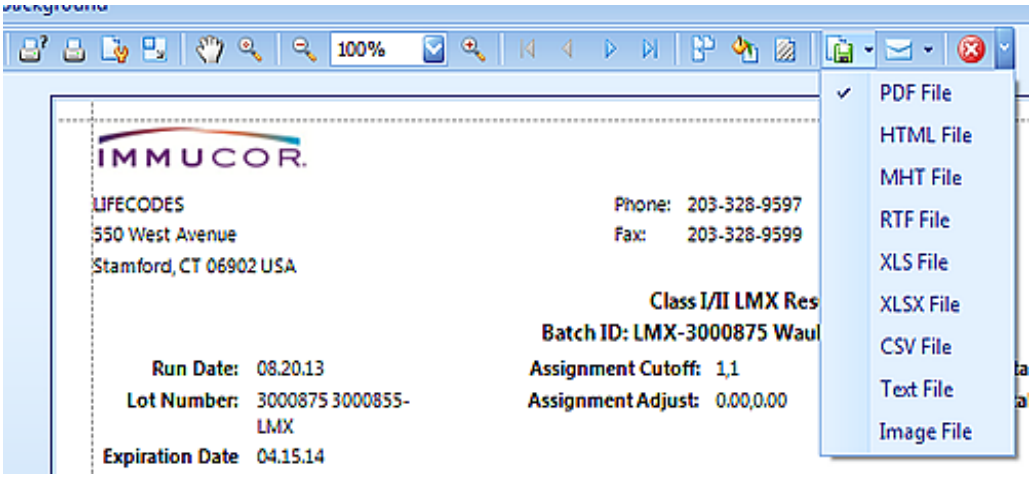
(PDF, HTML, MHT, RTF, Excel, CSV, txt, or Image File)

1) Generate a report from the *Reports* tab in the *LifeScreen Analysis* tab.



2) Once a report appears on the screen, click the **Export Report** icon in the upper right toolbar.

3) The dialog box that appears provides several different options for exporting/saving the report.



Exporting Summary Results

Many Laboratory Information Systems require simple export files that list only the samples and results. This file can be generated directly from the **Export** button on the homepage. *See "Export Results"*

CHAPTER 5: LIFECODES ID ANALYSIS

This chapter contains information on the tools available to analyze LIFECODES ID results (ID).

Importing ID Results into MATCH IT!

If an Automated Batch was not created and data needs to be manually imported into the software, the appropriate EDS file must first be imported followed by the csv file.

Importing EDS files

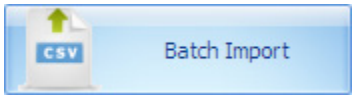
Before importing ID data, the information necessary for analyzing the data generated by the Luminex instrument must be imported. The information is provided in lot-specific EDS files.

1) Click **Lot Information Import** found on the Home tab of MATCH IT!. The Open dialog box will appear.

2) Navigate to the location, e.g., desktop, of the EDS file(s). Select all appropriate files that need to be imported. Use Ctrl + left mouse button to select more than one EDS file at one time.

3) Click **Open**. A message will appear when all lots have been successfully imported.

Manually Importing CSV Files



1) Click **Batch Import** from the homepage. This will open the *Open* dialog box

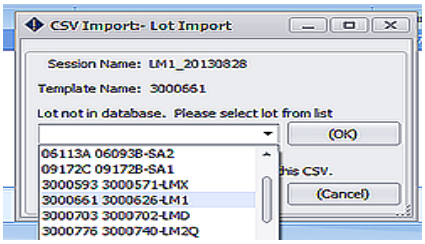
2) Navigate to the location of the CSV file(s). If importing from the computer connected to the Luminex, CSV files can be found in C:\My Batches\Output on IS 2.3 systems and at C:\ProgramData\Luminex\xPONENT31\Output on xPONENT systems.

3) Select all CSV files to be imported. Use Ctrl + left mouse button to select more than one CSV file at one time.

4) When the file is selected, the analysis is done automatically during the import process. Once the csv file has been imported, it will appear on the Antibody Home tab under ID.

Note: *A* ***CSV Import: Lot Import*** *may appear after selecting a csv file. This can be due to:1) the appropriate EDS file not being imported, 2) the*

EDS file not being available *See "Lot Availability"* *, or 3) the lot number not being indicated on the CSV file.*

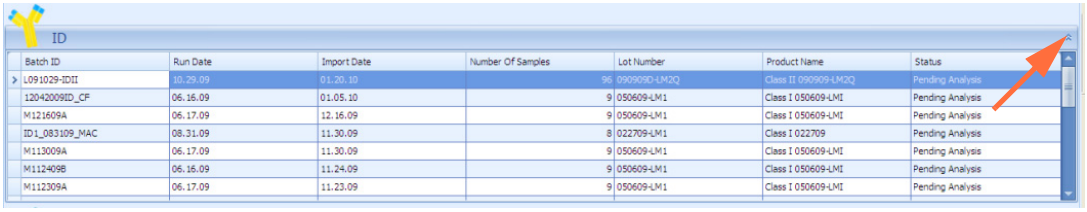


+

Opening a Batch

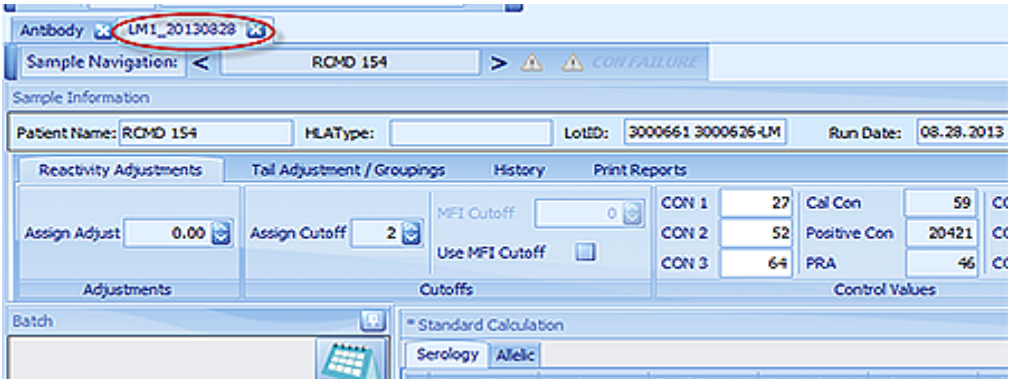
Direct Selection

1) Click the arrow to first expand the *ID* section.



2) Double click the batch name found on the *Antibody Home* tab under *ID.*

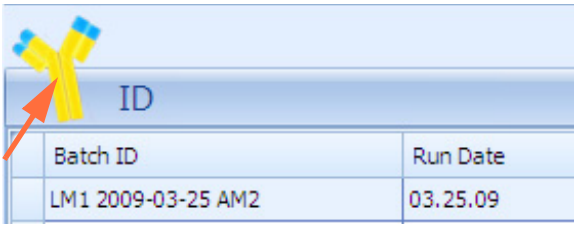
3) The batch name will display on a tab above the Sample Navigation ribbon. All sample results appear in the middle section of the tab. Individual sample IDs within the selected panel are listed in the left section of the tab under the batch name.



Date Range Selection

Rather than selecting an individual batch, a range of dates can be selected, which will result in all batches run in that range being selected.

1) Right click the antibody symbol as shown below.



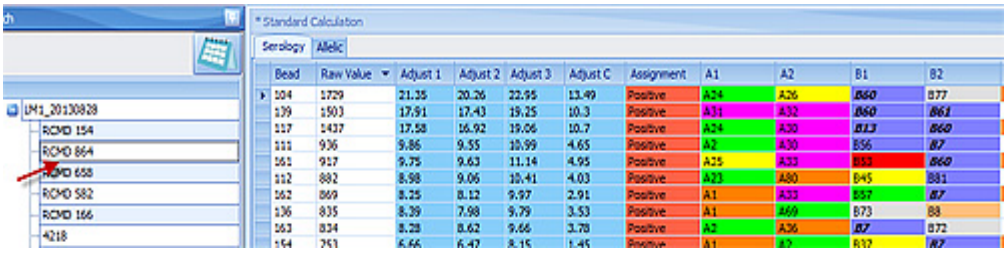
2) A pair of calendars with a start and end date will open. Select the desired range and click OK.

3) The batch results are displayed under the *ID Analysis* tab. All sample results appear in the middle section of the tab. Individual sample IDs within the selected panel are listed in the left section of the tab under the batch name.

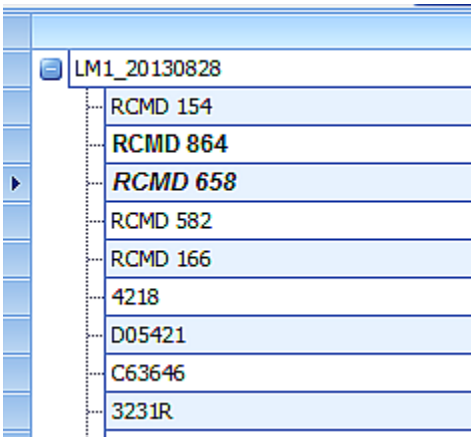
Viewing a Sample within a Batch

Navigating to a Particular Sample

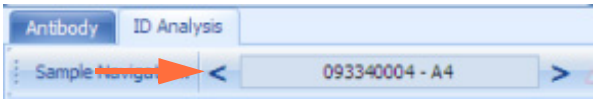
To go to a particular sample in the batch, left click the sample ID in the window. The software will open this sample.



Within the Batch List completed samples will be highlighted with bold text; completed and approved samples will be bold and italicized.

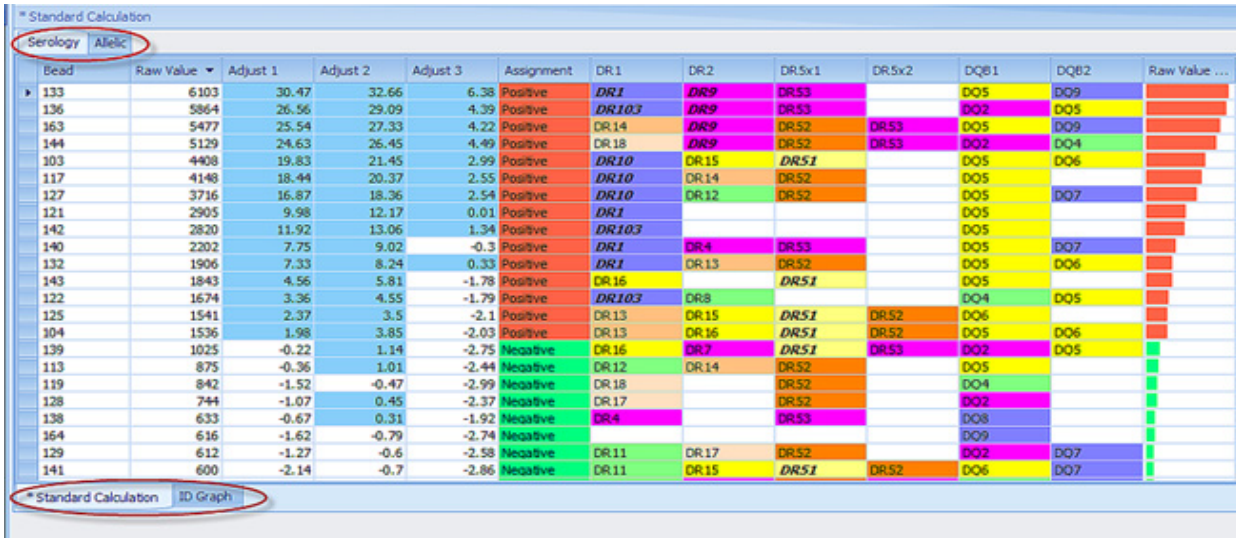


The upper arrows can also be used to move from sample to sample.



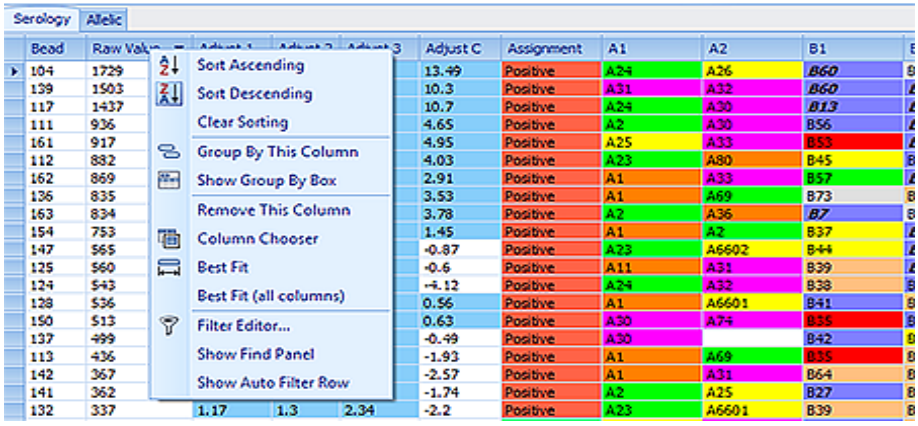
Tabs in the Analysis screen

Once a Sample is selected, the Standard Calculation tab will display the bead ranking grids. The user can select between Serology and Allelic phenotype displays by clicking on the tabs at the top of the grid. Both tabs look similar and can be customized as described in the below sections. Tail Analysis will only be available in the grid designated in **Preferences**. *See "Analysis Options:"*



Column Customization

Columns can be customized to meet the user's needs by right clicking a column header. The customization will be saved for the user for future data review.



Changing Sort Order

The sample by default will display beads in descending order of *Raw MFI*. This can be changed two different ways.

1) Right click a column header and choose *Sort Ascending* or *Sort Descending*. The sort order will be saved when viewing future batches.

2) Left clicking a column header will also sort. Once the column is clicked, a downward or upward triangle will appear showing the direction of order; descending or ascending in value, respectively.

Column Removal/Addition and Column Width

1) To remove a column, right click the column and choose *Remove This Column*.

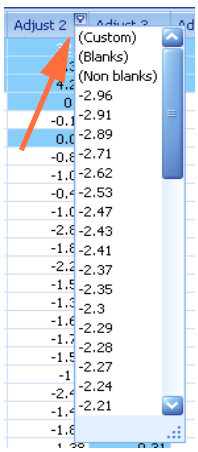
2) To add a column that has been previously removed, right click the column and choose *Column Chooser*. The **Column Customization** window will appear displaying the columns that have been removed. Right click the column to add and choose *Show This Column*.

The **Column Customization** window also allows the user to drag and drop columns into the window to customize the layout.

3) To change the width of a column, right click the column and choose *Best Fit* or *Best Fit (all columns)*. The columns will size according to the values in the column and apply it to only that column or to all columns depending on what is chosen.

Displaying Selected Bead Values

Specific beads containing particular information can be viewed.



1) Hover over a column. A small *pin* will appear in the upper right corner of the chosen column.

2) Left click the *pin*. All values or text within that chosen column will be listed.

3) Choose any one of the values or text items displayed. When chosen, only the bead(s) that includes that value or text within that column will display.

Note: All of the sub-windows and columns may be resized by placing cursor on the line to be moved and dragging the mouse.

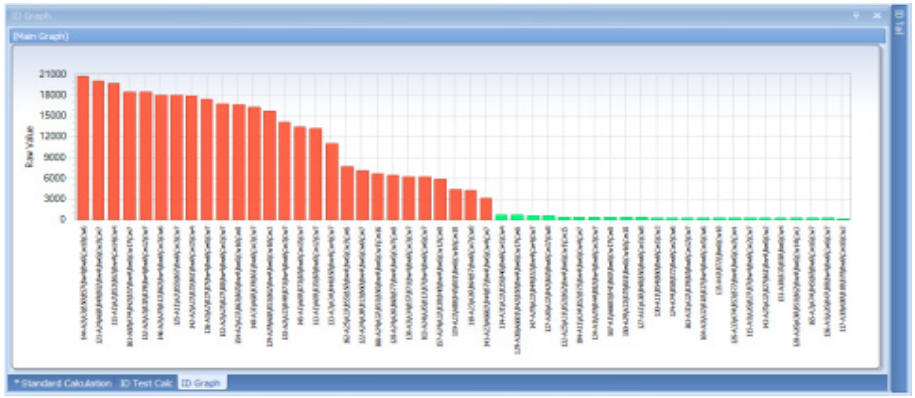
Graphical Display

Antigen Graph

A graph of *Raw MFI vs. Bead (Antigens)* is displayed by default on the main page in a separate tab. The graph enables the user to visualize the strength of each bead relative to the sample and the assignment for each bead; red is a positive assignment while green is a negative assignment. There are two views for the graph:

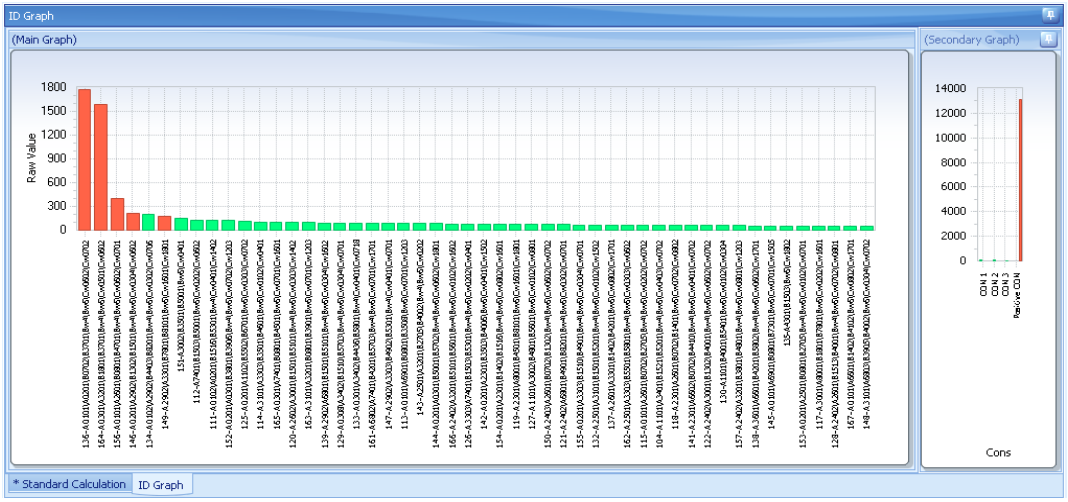
- The **Standard Mode** displays a graph with the positive and negative assignments for beads based on the settings for *Assign Cutoff* and *Assign Adjust.* *See "Preferences"*

- The **MFI Cutoff** displays a graph with positive and negative assignments for beads based on the MFI value the user sets as the cutoff.



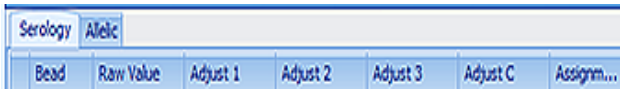
Control Graph

A graph of *Raw MFI vs. Controls (Positive control and 3 negative CONS)* is displayed next to the Antigen Graph only when *Raw MFI vs. Bead (Antigens)* is chosen as the main graph.



Additional Graphing Features

•To change the y-axis for what is displayed in the graph, click any of the column headers in the bead ranking view; *Adjust 1, Adjust 2, Adjust 3, or Adjust C*.

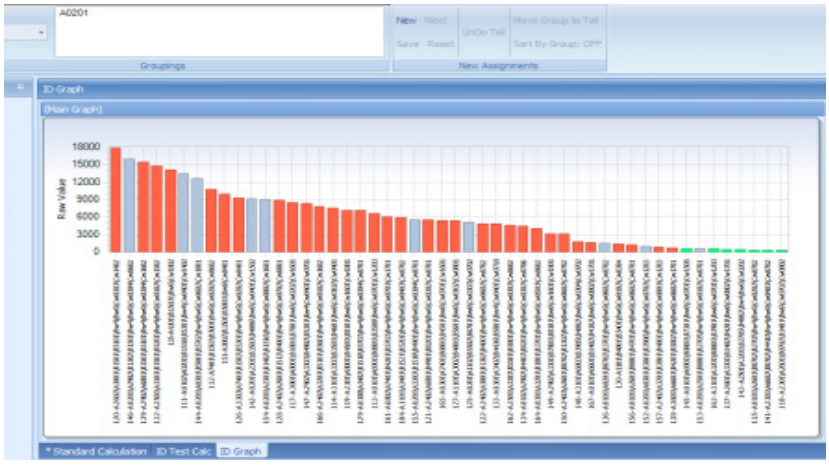


•To change the bead order (antigen order) of the x-axis, right click anywhere within the graphing area and choose *Sort By*. A selection of antigen sorting options will appear.

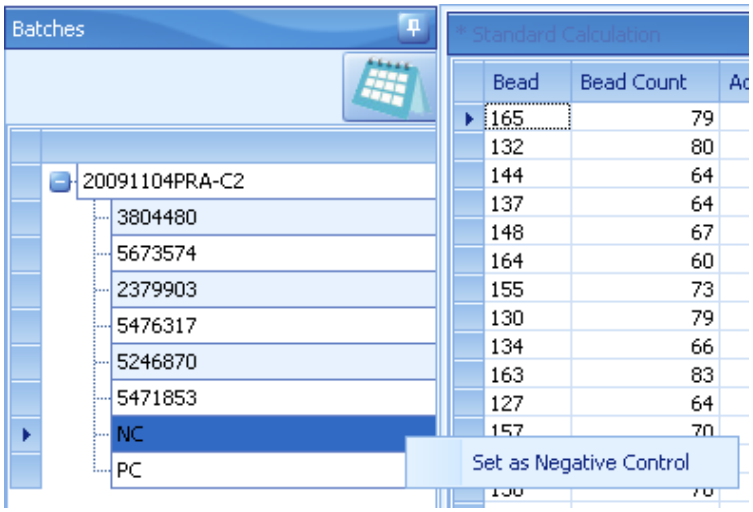
•To change the graph type, i.e. from a bar graph to a line graph, right click anywhere within the graphing area and choose *Gallery*. A selection of graph types will appear.

•To zoom, right click anywhere within the graphing area and choose *Zoom*. Use the mouse to make a box around the area to zoom.

•If a *Group* is selected, the graph will highlight the bars for the beads containing an antigen in the selected *Group*. The grey bars represent beads containing antigens within the selected *Group*.



•To overlay a particular sample; i.e. the negative control, onto each sample graph, right select the sample of choice from the batch window and right click to choose **Set as Negative Control**. Now when viewing any of the sample graphs within the batch, the sample and the set negative control sample will display.



Note: The user may select different samples within the batch to be designated as the Negative Control. Once this option has been turned on for a batch it cannot be turned off.

Calculations and Displayed Values

Calculations

To determine the adjusted value for a bead, divide the individual bead median MFI by the MFI for each Negative Control Bead (CON1, CON2, CON3). From these values, subtract the Background Adjustment Factor (BAF) for the appropriate bead/CON combination. The BAF is a pre-determined MFI ratio for each bead/CON combination to compensate for background noise due to bead variation and can be found on the lot-specific Recording Sheet provided with the kit.

(Individual Bead MFI ÷ CON1 MFI) - BAF = Adjusted Ratio 1

(Individual Bead MFI ÷ CON2 MFI) - BAF = Adjusted Ratio 2

(Individual Bead MFI ÷ CON3 MFI) - BAF = Adjusted Ratio 3

The Class I & II ID kits also employ a fourth negative control calculation, "CalcCON", based on performance of the non-reacting antigen-containing beads.

(Individual Bead MFI ÷ CalcCON) - BAF = Adjusted Ratio 4

CalcCON = MFI lowest ranked antigen bead + 20

•By default, a positive value for two or more of the four calculations indicates a positive bead reaction. This setting can be changed by the user. *See "Preferences"*

For LIFECODES Class I ID:

The percent PRA (Panel Reactive Antibodies) is calculated by:

% PRA = (# of pos bead reactions ÷ # of beads in the assay) x 100

# of beads in the assay does not include control beads

For LIFECODES Class II IDv2:

% PRA = [(# of pos reacting DR-containing beads + # of neg reacting DR-containing beads that also contain an assigned DQ antigen that is 100% pos in the enriched beads) ÷ Total # of DR-containing beads] X 100

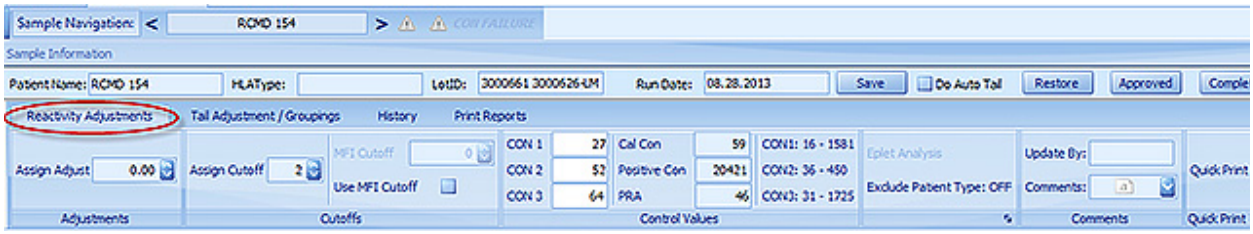
# of beads in the assay does not include control beads

Making a Positive or Negative Assignment

A bead is assigned as positive or negative based on user defined analysis parameters or by manual MFI cutoffs.

By Standard Mode

If preferences have not already been set for these parameters or an override is necessary for a particular sample, they can be changed in the *Reactivity Adjustments* tab. *See "Preferences"*



•**Assign Adjust** sets the positive threshold for all adjusted values. Once the value box is selected, the up and down arrows can be clicked to the desired value or the up and down arrow keys may be used. A value can also be typed directly into the white box. *The default setting is 0.*

•**Assign Cutoff** is a score of 1 to 4. It indicates the number of calculations, against different controls, that must be positive for the sample to be assigned as positive. This allows the user to show samples positive with only 1 out of 4 controls positive, 2 out of 4 controls positive, 3 out of 4 controls positive, or all 4 controls positive. *The default setting is 2.*

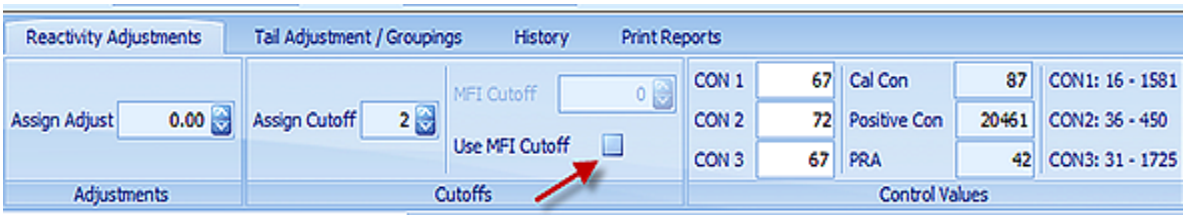
If the parameters are changed, the user must save the change prior to manual tail analysis. To save the changes Click **Save.**

If **AutoTail** is checked then the tail is automatically calculated.

*Note: If Eplets are assigned and reactivity adjustment changes are made using **Assign Adjust** or **Assign Cut-off**, the Eplet assignment will clear. To assign eplets using the new cut-offs, click **Eplet Analysis.***

By MFI Cutoff

Beads can be assigned as positive or negative by manually assigning an MFI cutoff. There are three ways to assign an MFI cutoff.



1) Under the *Reactivity and Adjustments* tab, click the box next to *Use MFI Cut-off*.

2) The MFI value box is now available. Select the value box. The up and down arrows can be clicked to the desired value or the up and down arrow keys may be used. A value can also be typed directly into the white box. Once the value is entered, click the graph to view the new cutoff.

3) An alternative to step 2 is to right click anywhere on the graph and choose *Graph Edit*. The *Cut Off* bar will then be visible and can be moved to the desired value.

4) Click **Save**.

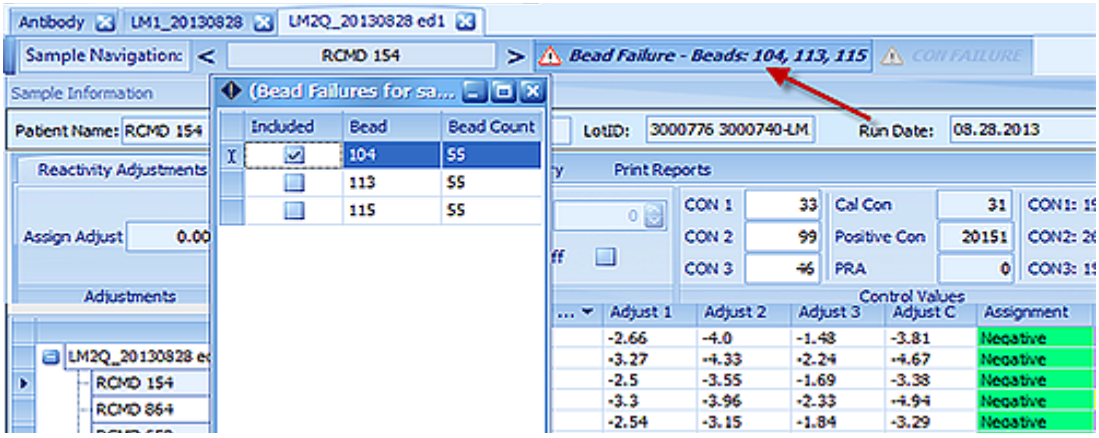
5) To apply an MFI cut-off to all samples for Class I or Class II, a user may select MFI mode in the **ID** tab of **Preferences** window. MFI cut-offs can be set individually for Class I and Class II The up and down arrow keys may be used. A value can also be typed directly in the white box. The user must then select the box that indicates that the value should be applied to data upon import.

*Note: If Eplets are assigned and reactivity adjustment changes are made using **MFI mode,** Eplet assignments will clear. To assign eplets using the new cut-offs, click **Eplet Analysis.***

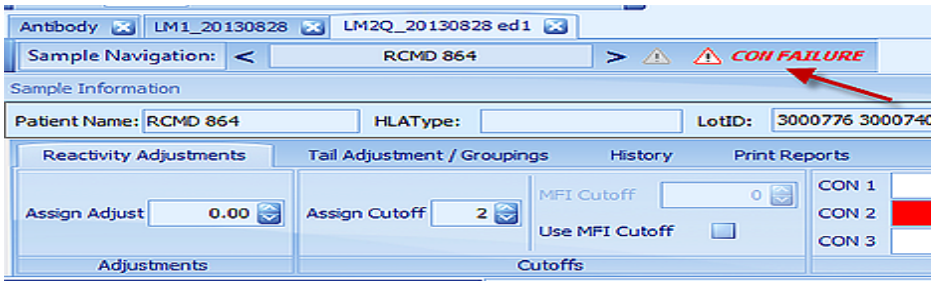
Batch Failures

Bead Count Failure

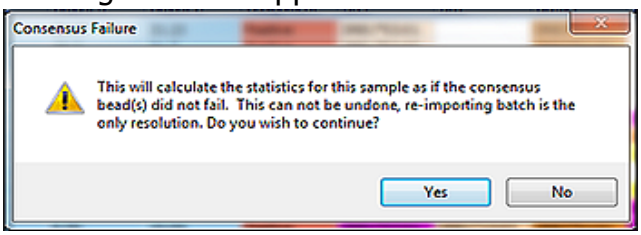
- If a sample fails to meet the minimum bead count for a particular result, the bead will be flagged as *FAILED*. To override the failure, doule click the message and select the failed beads to include in the analysis



•If a CON bead fails to meet the minimum bead count, the software will report all beads as failed. To override the failure, click the message.



•A message box will appear to confirm the override.


Consensus Failure
This will calculate the statistics for this sample as if the consensus bead(s) did not fail. This can not be undone, re-importing batch is the only resolution. Do you wish to continue?
Yes
No

The source of all failures is listed in the ID Analysis header. By clicking the *FAILED* message, the user has the option to include failed beads in the analysis.

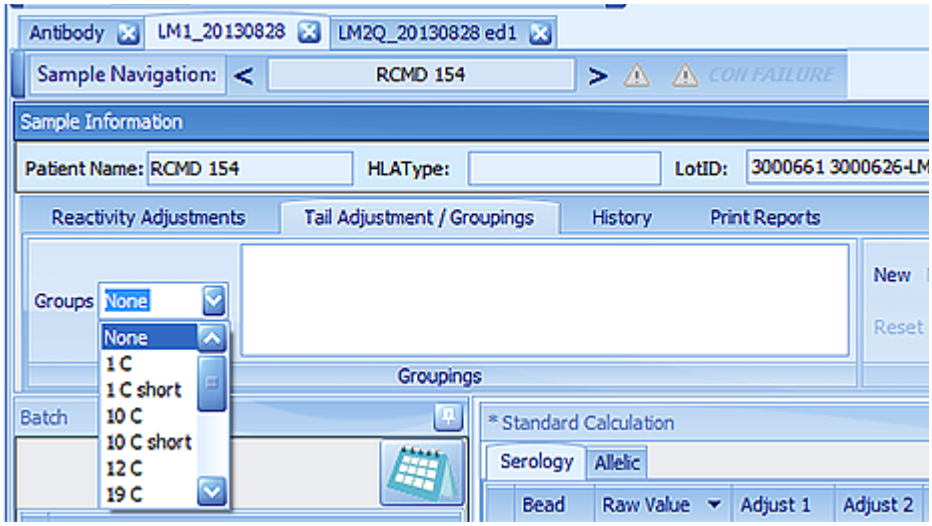
Note: If a sample has both CON failures AND bead failures, the CON failure must be overidden before the failed beads can be included.

Tools for Making an Assignment

Groupings

The **Groups** drop-down box is a list of user defined HLA Groups. By selecting a particular group, the antigens present within the particular

group will be highlighted in the bead ranking. *See "Antibody Reactivity Groups"*



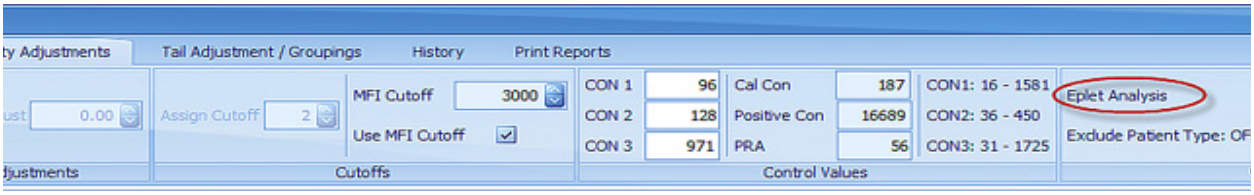
Color-Coded Antigen(s):

The user can color code antigens or groups of antigens to provide easier viewing. This feature is intended as a visual aid. The *.xml* file provided on the Immucor website contains color-coded antigens but they may be changed.

Eplet Analysis

Added Epitope Analysis can be run at a sample level. If epitopes are not calculated upon import click the Eplet Analysis button to assign available epitopes. Eplets will be calculated based on Positive beads (Eplets are not calculated on assigned antigens).

*Note: Eplet Analysis feature will not work if **Use Serology** is checked in **Preferences**. If the user un-checks **Serology** in **Preferences** after a batch has imported, the batch must be closed and then re-opened for those changes to take effect.*



Tail Analysis

Note: Tail Analysis is by default a serology tail analysis. To change to a 4-digit tail analysis See "Antibody Parameters:"

When **Exclude Patient Type** is turned **ON** on in the *Reactivity Adjustment tabs* (if not already selected under *Preferences*) excluded antigens

will be listed under the **Excluded Antigens** window in IDTail and not available for Tail Analysis

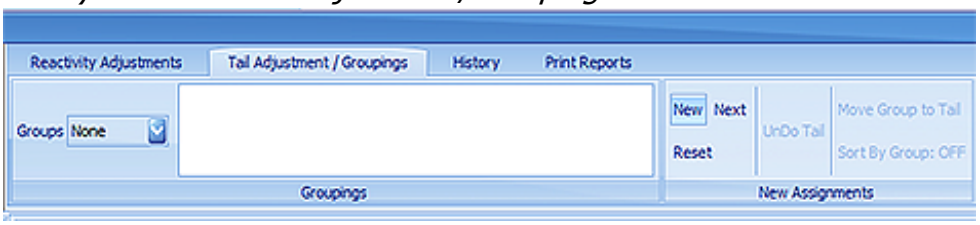
Automatic Tail

The software will assign a tail automatically if *Perform Auto Tail Analysis* is chosen as a preference or if *Do Auto Tail* is checked in the *Patient Information* key. *See "Tail Parameters (ID only):"* The tail will then be automatically assigned when imported.

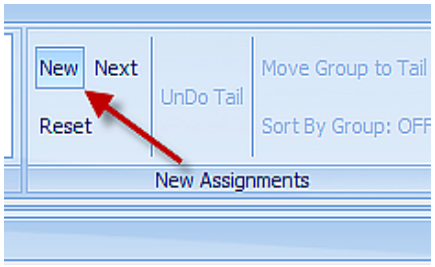
Manual Tail

1) Tail preferences should first be set in the preference window. *See "Tail Parameters (ID only):"*

2) Go to the *Tail Adjustment/Groupings* tab.

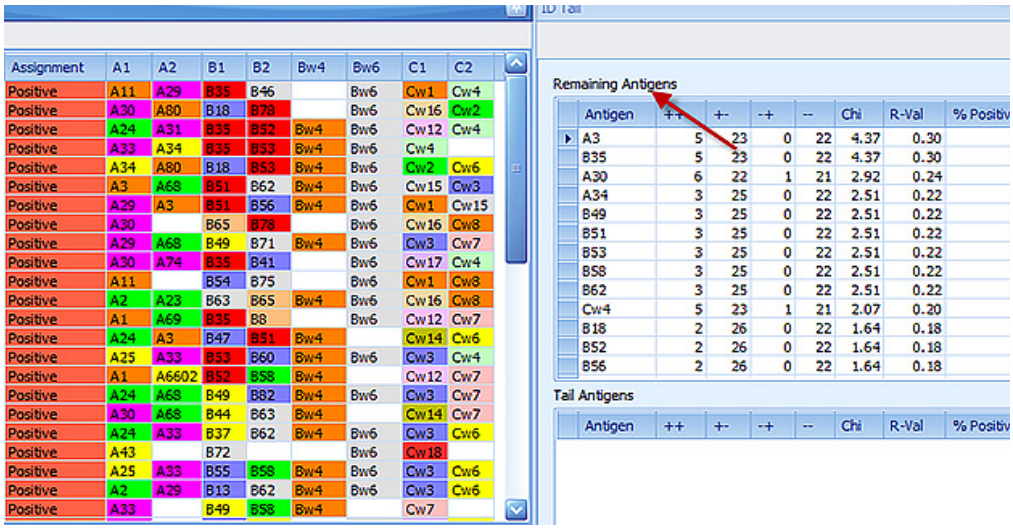


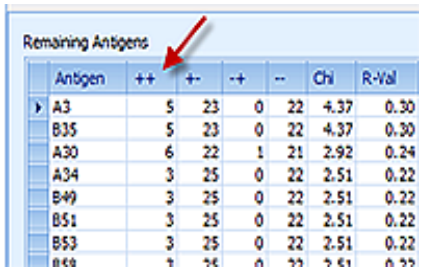
3) Click **New**.



The antigens listed are those that meet the **Tail Parameters** previously set for a particular sample. *See "Tail Parameters (ID only):"* The following statistics are displayed:

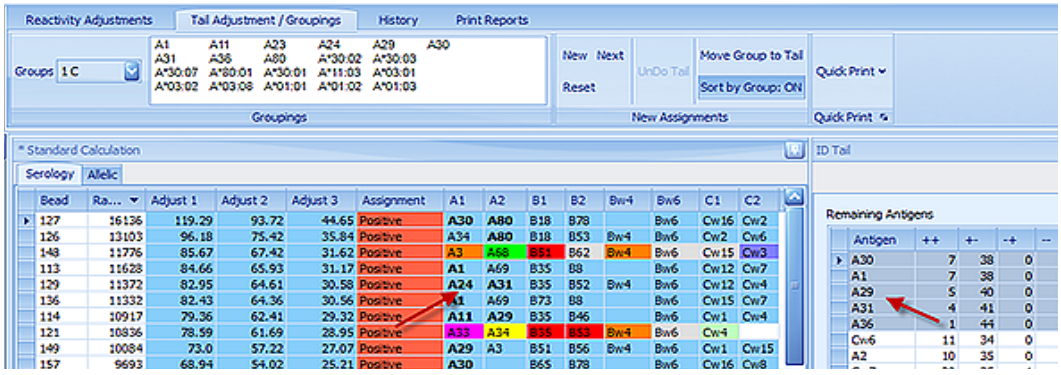
a) # of true positives(++)
b) # of false positives (+ -)
c) # of false negatives (- +)
d) # of true negatives (- -)
e) Chi^2
f) R Value
g) % Positive
h) *Strength Index* (Avg. MFI of all beads containing the antigen)


ID Tail
Assignment A1 A2 B1 B2 Bw4 Bw6 C1 C2
Positive A11 A29 B35 B46 Bw6 Cw1 Cw4
Positive A30 A80 B18 B78 Bw6 Cw16 Cw2
Positive A24 A31 B35 B52 Bw4 Bw6 Cw12 Cw4
Positive A33 A34 B35 B53 Bw4 Bw6 Cw4
Positive A34 A80 B18 B53 Bw4 Bw6 Cw2 Cw6
Positive A3 A68 B51 B62 Bw4 Bw6 Cw15 Cw3
Positive A29 A3 B51 B56 Bw4 Bw6 Cw1 Cw15
Positive A30 B65 B78 Bw6 Cw16 Cw8
Positive A29 A68 B49 B71 Bw4 Bw6 Cw3 Cw7
Positive A30 A74 B35 B41 Bw6 Cw17 Cw4
Positive A11 B54 B75 Bw6 Cw1 Cw8
Positive A2 A23 B63 B65 Bw4 Bw6 Cw16 Cw8
Positive A1 A69 B35 B8 Bw6 Cw12 Cw7
Positive A24 A3 B47 B51 Bw4 Cw14 Cw6
Positive A25 A33 B53 B60 Bw4 Bw6 Cw3 Cw4
Positive A1 A6602 B52 B58 Bw4 Cw12 Cw7
Positive A24 A68 B49 B82 Bw4 Bw6 Cw3 Cw7
Positive A30 A68 B44 B63 Bw4 Cw14 Cw7
Positive A24 A33 B37 B62 Bw4 Bw6 Cw3 Cw6
Positive A43 B72 Bw6 Cw18
Positive A25 A33 B55 B58 Bw4 Bw6 Cw3 Cw6
Positive A2 A29 B13 B62 Bw4 Bw6 Cw3 Cw6
Positive A33 B49 B58 Bw4 Cw7
Remaining Antigens
Antigen ++ +- -+ -- Chi R-Val % Positiv
A3 5 23 0 22 4.37 0.30
B35 5 23 0 22 4.37 0.30
A30 6 22 1 21 2.92 0.24
A34 3 25 0 22 2.51 0.22
B49 3 25 0 22 2.51 0.22
B51 3 25 0 22 2.51 0.22
B53 3 25 0 22 2.51 0.22
B58 3 25 0 22 2.51 0.22
B62 3 25 0 22 2.51 0.22
Cw4 5 23 1 21 2.07 0.20
B18 2 26 0 22 1.64 0.18
B52 2 26 0 22 1.64 0.18
B56 2 26 0 22 1.64 0.18
Tail Antigens
Antigen ++ +- -+ -- Chi R-Val % Positiv



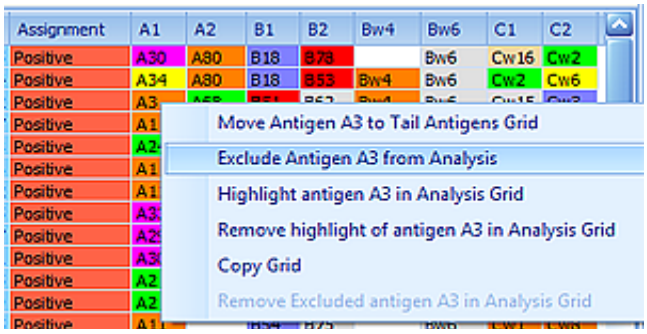
4) **Sorting:** The data can be sorted by any of the headers in the ID Tail Window. Click the desired header and the data will sort in descending or ascending order. *The default ranking is descending by RVal.* A sort order change here does not impact the AutoTail sorting or the function of the **Next** button. Default sort order can only be changed in **Preferences**. *See "Tail Parameters (ID only):"*

5) **Highlighting Groupings:** A particular group can be highlighted within the *Available Tail Antigens* by selecting the appropriate group in the dropdown menu found in the Tail Adjustment/ Grouping tab. The antigen(s) included in the group that meet the **Tail Parameters** set will be highlighted in gray under **Remaining Antigens**. To bring the antigens within the selected group to the top of the **Remaining Antigens**, turn **Sort by Group** ON.



6) If **Sample Antigens** were not entered into the sample list, they can still be excluded from the tail analysis.

To add or exclude antigens to/from the tail, right Click an antigen within the grid and choose **Exclude Antigen X from Analysis**.



7) To add an antigen to the tail, double click the antigen found in the *Remaining Antigens* window or double click the antigen in the *Bead Ranking* grid. The antigen is added to the tail. The remaining antigens, not included within the tail, are then re-calculated and listed for further selection.

8) The following **Tail Actions** can also be used when adding to the tail:

a) *Next* moves the top-ranking antigen into the tail.

b) Right click within the grid and choose *Move Antigen X to Tail Antigens Grid*

c) *Move Group to Tail* will move all antigens within the selected Group into the tail

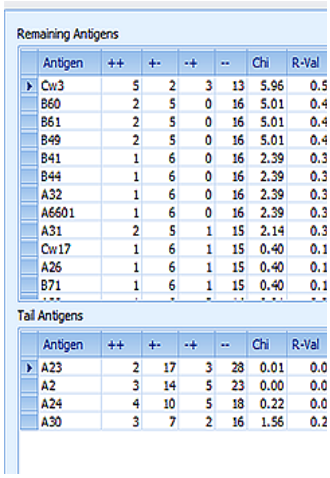
d) *Undo Tail* will remove the most recent tail addition

e) *Save* will save any antigens placed into the tail analysis for the report

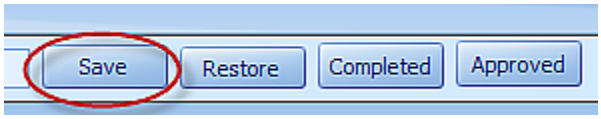
f) *Reset* returns the tail to the previously saved tail

g) *New* returns any antigens moved to the tail to the antigen list and allows the user to start again.

9) Continue loading tail until complete or until all antigens desired are added to the tail. Antigens will be bold and italicized in the bead ranking screen.



10) Click **Save** before moving to the next sample.

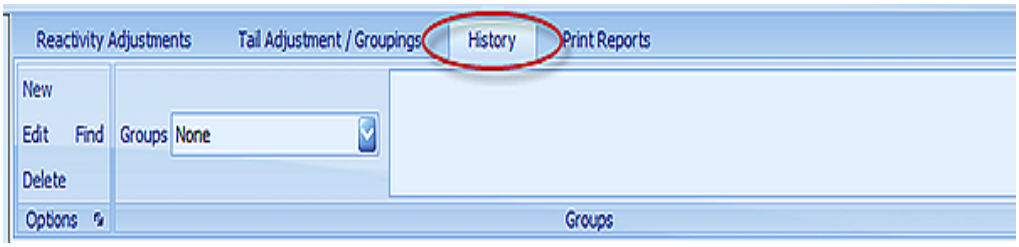


Creating a History

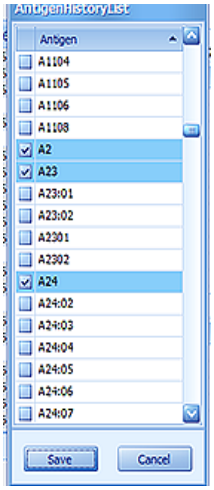
The user has the option of creating a *Snapshot of the History* for a particular sample. In the *History* tab, a user has the ability to load antigens to create a reactivity group specific to the sample. This will enable a user to monitor changes in antibody status across kits and over time.

New History

1) Go to the *History* tab.



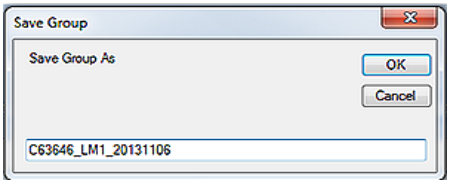
2) Click **New**.



3) The previously assigned antigens (either automatically or manually) will be checked and highlighted in the window which appears. Additional antigens may be added to the history by checking the box next to the antigen *(Note: This will not change the saved tail results)*.

4) Click **Save**.

5) Confirm the decision to make a history snapshot of the results and name the *Antigen History Group*.



Applying a Previously Created History to a New Sample

A previously created *History* can be viewed with a new sample.

1) Go to the *History* tab of the new sample.

2) Click **Find.**

3) Type either the name of the *Antigen History Group* or a key component of the name, i.e. first letter.

4) The history of the sample will display.

View Current Assigned History for a Sample

1) Go to the *History* tab of the new sample.

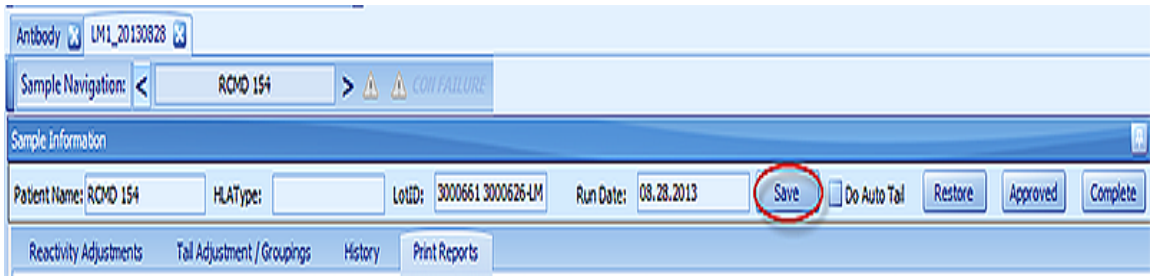
2) Select the *History* from the dropdown.

3) The Saved *History Snapshot* will be highlighted.

Approving the Results of the Analysis

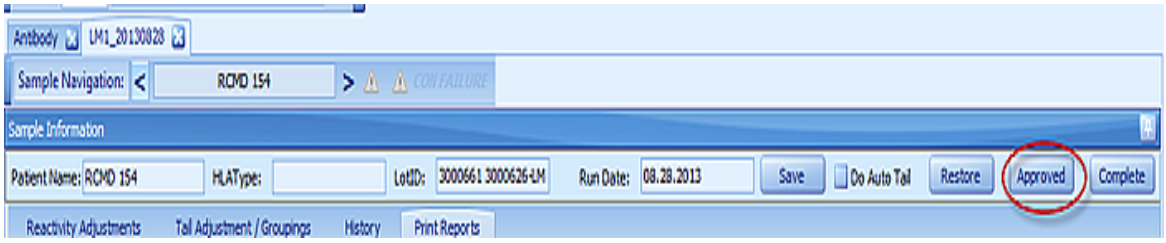
Approving Results

When **Save** is clicked, the analysis for the sample is saved but can be analyzed again.



When **Restore** is clicked, the sample will revert to the most recently saved data/assignments.

Once analysis is complete and no additional changes need to be made for a particular sample, click **Complete**. Only a *Lab Technician* or *Lab Supervisor* may make changes to a sample by clicking **Complete** again. When <u>all</u> samples in a batch have been designated as **Complete**, the batch status will be listed as **Completed** on the home page and signify they are ready for **Approval.**



Once the analysis of completed results has been reviewed, click **Approved**. Once clicked, changes can no longer be made except by a *Lab Supervisor* by clicking **Approved** again. When all samples within a batch

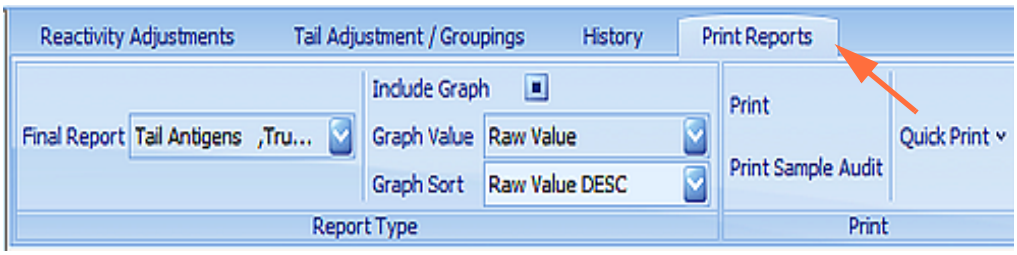
are designated as Approved, the batch status will list the batch as **Approved** on the home page.

Reporting and Printing

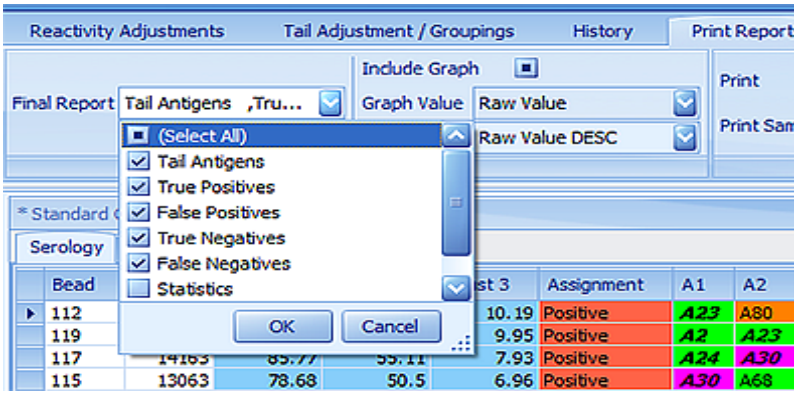
After the sample has been analyzed, (automatically or by using the manual tail analysis features) the user has the ability to customize a report.

Customizing a Final Report

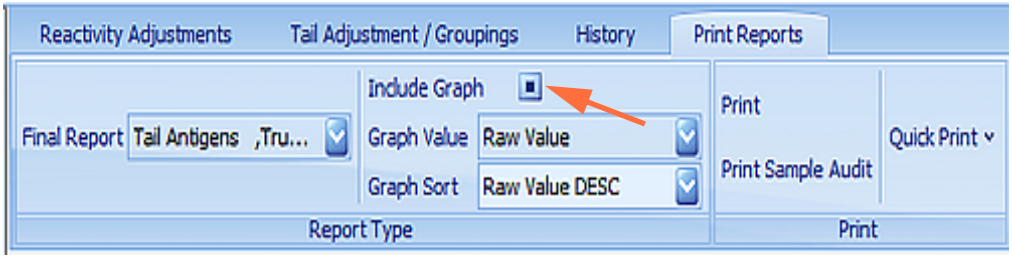
1) Once the results have been Approved, go to *Print Reports* tab. Approving the results is not a requirement to print.



2) Click the drop down arrow next to *Final Report* and select the items to include in the Final Report.



3) A graph can be included in the report as well by checking the box next to *Include Graph*. *Graph Value* (y-axis) and *Graph Sort* (x-axis) may also be customized by clicking the drop down arrow and selecting the appropriate choice.



3) Once a report appears on the screen, click the *Print* icon in the upper toolbar.

Quick Print

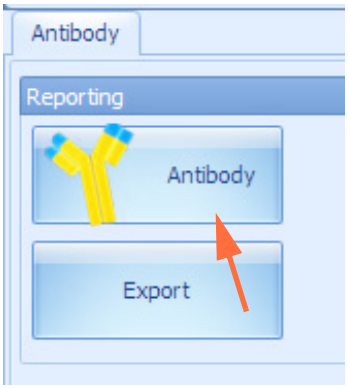
Either a *Bead Ranking report* or *Graph* can be printed by clicking **Quick Print**.

The **Bead Ranking Report** is sorted as it is sorted in the grid. All antigens associated with each bead will be listed, as well as whether the bead was assigned as **Positive** or **Negative**.

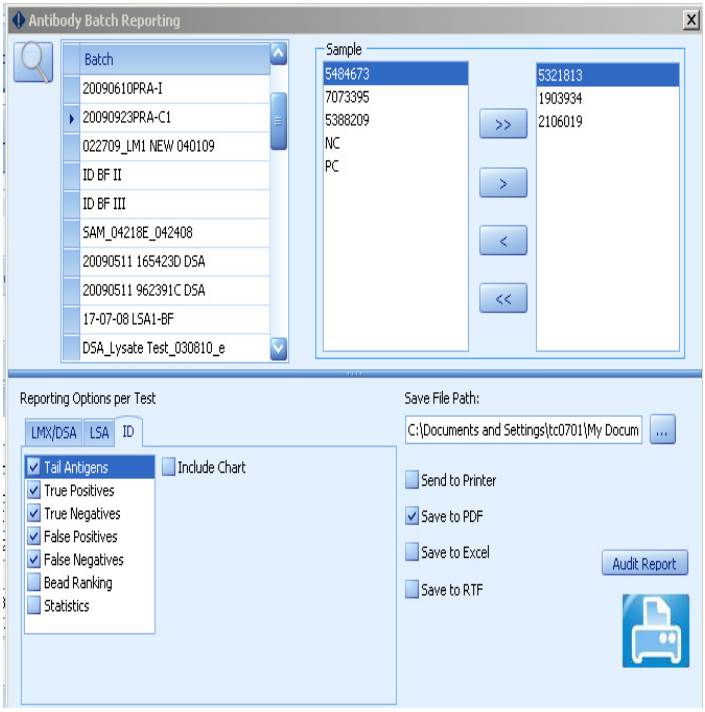
Batch Reporting

1) Go to the *Home Antibody* tab.

2) Click the *Antibody* icon.



3) Click the magnifying glass to display a calendar.



4) Choose the date or range of dates of when the batch was imported.

5) Batches will display in the *Batch* column. Double click the batch of choice. All samples within the batch will display in the *Sample* colunmn.

6) Use the arrows to move the samples to the *Print (right)* column which will include them in the batch reporting.

7) Once all desired samples have been moved to the *Print (right) column*, choose the ID tab under **Reporting Options**. Choose the items to include in the report.

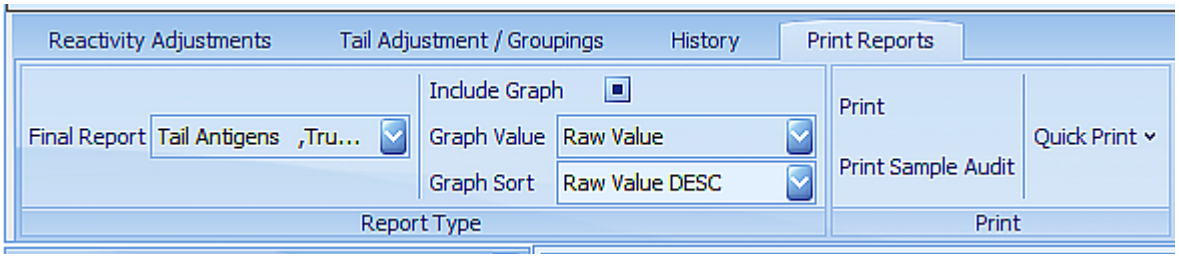
8) Select desired **Printing Option**: *Send to Printer, Save to PDF, Save to Excel,* or *Save to RTF*. Multiple options may be chosen. If *Save to PDF*, *Save to Excel*, or *Save to RTF* is chosen choose a *Save File Path*.

9) Click the *Print icon*. A dialogue box will appear stating that reports have been generated. Click **OK** to continue.

10) If an *Audit Report* is desired, click **Audit Report**. This report can only be generated in pdf format.

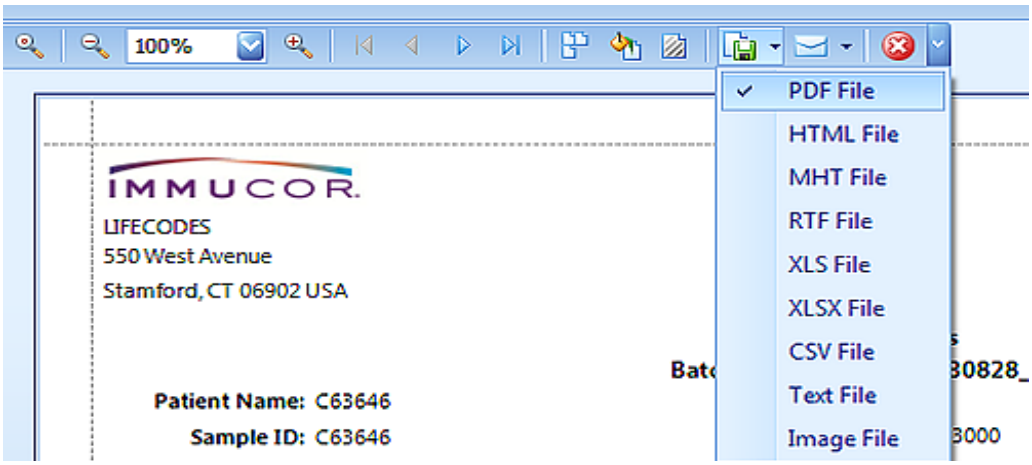
Exporting Reports

1) Generate a report from the *Print Reports* tab in the *ID Analysis* tab.



2) Once a report appears on the screen, click the **Export Report** icon in the upper right toolbar.

3) The dialog box that appears provides several different options for exporting/saving the report.



Exporting Summary Results

Many Laboratory Information Systems require simple export files that list only the samples and results. This file can be generated directly from the *Export* tab. *See "Export Results"*.

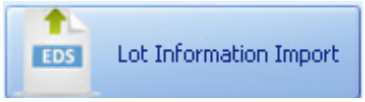
Chapter 6: LIFECODES Single Antigen Analysis

This chapter contains information on the tools available to analyze LIFECODES Single Antigen Class I and II, C3d, and LIFECODES Single Antigen-MIC (LSA).

Importing Single Antigen Results into MATCH IT!

If an Automated Batch was not created and data needs to be manually imported into the software, the appropriate EDS file must first be imported followed by the csv file.

Importing EDS files



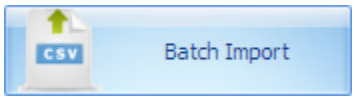
Before importing LSA data, the information necessary for analyzing the data generated by the Luminex instrument must be imported. The information is provided in lot-specific EDS files.

1) Click **Lot Information Import** found on the Home tab of MATCH IT!. The Open dialog box will appear.

2) Navigate to the location, e.g., desktop, of the EDS file(s). Select all appropriate files that need to be imported. Use Ctrl + left mouse button to select more than one EDS file at one time.

3) Click **Open**. A message will appear when all lots have been successfully imported.

Manually Importing CSV Files



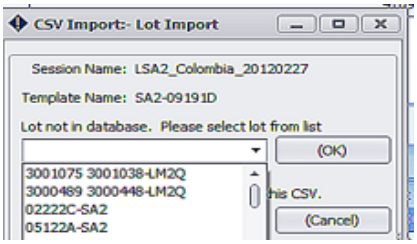
1) Click **Batch Import** from the homepage. This will open the *Open* dialog box

2) Navigate to the location of the CSV file(s). If importing from the computer connected to the Luminex, CSV files can be found in C:\My Batches\Output on IS 2.3 systems and at C:\ProgramData\Luminex\xPONENT31\Output on xPONENT systems.

3) Select all CSV files to be imported. Use Ctrl + left mouse button to select more than one CSV file at one time.

4) When the file is selected, the analysis is done automatically during the import process. Once the csv file has been imported, it will appear on the Antibody Home tab under *Single Antigen*.

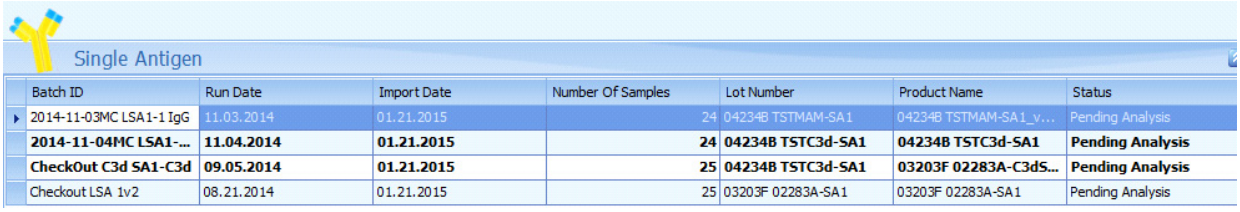
***Note:** A **CSV Import: Lot Import** may appear after selecting a csv file. This can be due to:1) the appropriate EDS file not being imported, 2) the EDS file not being available* *See "Lot Availability"* *, or 3) the lot number not being indicated on the CSV file.*



Opening a Batch

Direct Selection

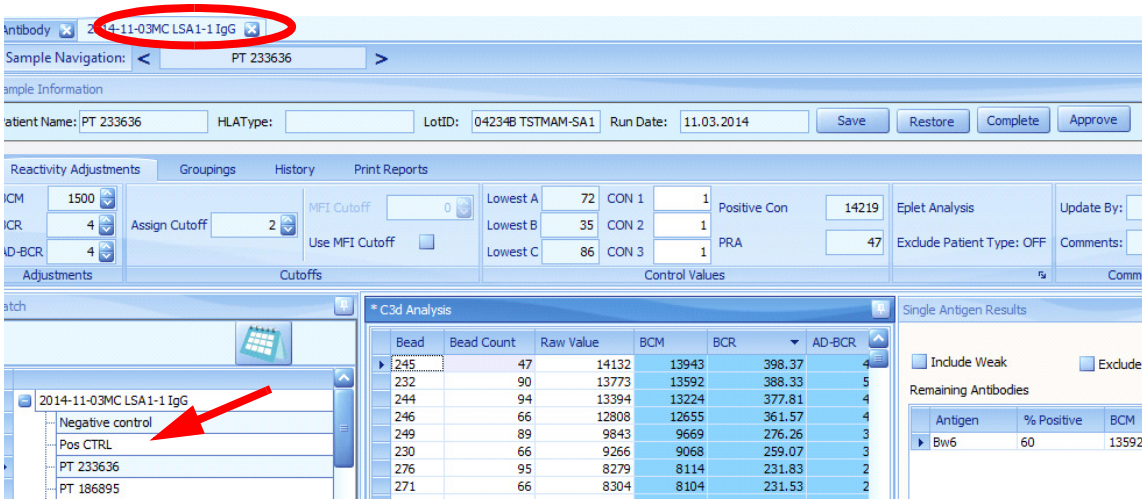
1) Click the arrow to first expand the *Single Antigen* section.


Single Antigen
Batch ID | Run Date | Import Date | Number Of Samples | Lot Number | Product Name | Status
2014-11-03MC LSA1-1 IgG | 11.03.2014 | 01.21.2015 | 24 | 04234B TSTMAM-SA1 | 04234B TSTMAM-SA1_v... | Pending Analysis
2014-11-04MC LSA1-... | 11.04.2014 | 01.21.2015 | 24 | 04234B TSTC3d-SA1 | 04234B TSTC3d-SA1 | Pending Analysis
CheckOut C3d SA1-C3d | 09.05.2014 | 01.21.2015 | 25 | 04234B TSTC3d-SA1 | 03203F 02283A-C3dS... | Pending Analysis
Checkout LSA 1v2 | 08.21.2014 | 01.21.2015 | 25 | 03203F 02283A-SA1 | 03203F 02283A-SA1 | Pending Analysis

2) Double click the batch name found on the *Antibody Home* tab under *Single Antigen*.

***Note**: C3d batches will display in **Bold** type on the home screen*

3) The batch name will display on a tab above the Sample Navigation ribbon. All sample results appear in the middle section of the tab. Individual sample IDs within the selected panel are listed in the left section of the tab under the batch name.

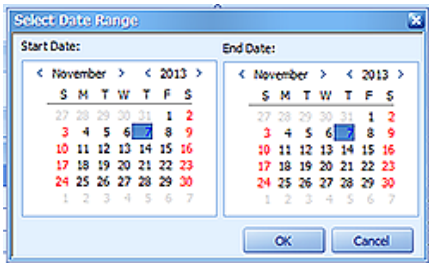


Date Range Selection

Rather than selecting an individual batch, a range of dates can be selected, which will result in all batches run in that range being selected.

1) Right click the antibody symbol as shown below.

2) A pair of calendars with a start and end date will open. Select the desired range and click OK.

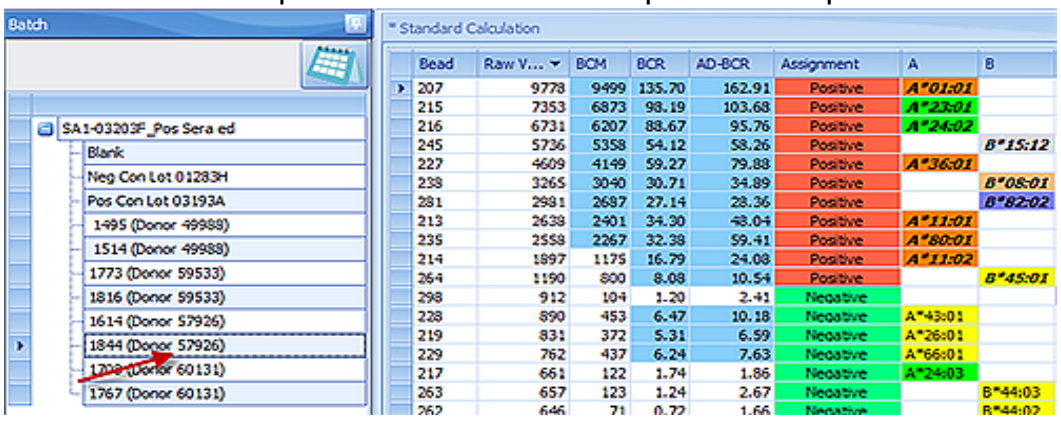


3) The batch results are displayed in an *LSA Analysis* tab. All sample results appear in the middle section of the tab. Individual sample IDs within the selected panel are listed in the left section of the tab under the batch name.

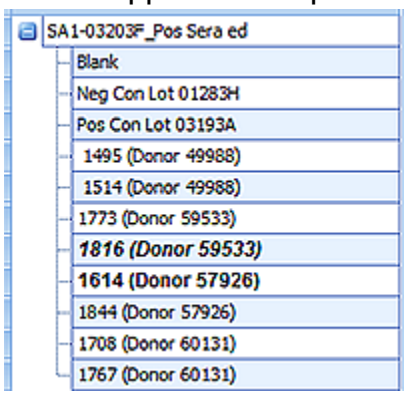
Viewing a Sample within a Batch

Navigating to a Particular Sample

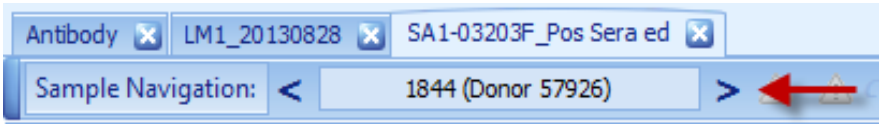
•To go to a particular sample in the batch, left click the sample ID in the left hand pane. The software will open this sample.



•Within the Batch List completed samples will be highlighted with bold text; completed and approved samples will be bold and italicized



•The upper arrows can also be used to move from sample to sample.



Overall Antibody Assignments

Automatic Assignments

The software will automatically assign antibody specificities for antigens that are 100% positive. The automatic assignments will appear in the *Single Antigen Results* window.

Calculations and Displayed Values

Calculations for LSA

To determine the adjusted value for a bead, first subtract the Background MFI from the RAW MFI to generate the *BCM (Background Corrected MFI Value)* for each individual bead. The Background MFI is the background noise due to bead variation and can be found on the lot-specific Recording Sheet provided with the kit.

Divide the *BCM* by the MFI of the Calculated Control (CalcCON) of its respective locus to generate the *BCR (Background Corrected Ratio)*. The CalcCON for each locus is the Raw MFI value of the lowest ranked antigen bead for that locus.

BCM ÷ CalcCON MFI for locus 1= BCR for antigen 'x' from locus 1

BCM ÷ CalcCON MFI for locus 2= BCR for antigen 'y' from locus 2

BCM ÷ CalcCON MFI for locus 3= BCR for antigen 'z' from locus 3

To generate the *AD-BCR (Antigen Density Background Corrected Ratio),* normalize BCR by dividing this number by the relative amount of antigen on each bead as found in the lot-specific Recording Sheet.

Refer to the lot-specific Recording Sheet provided with the kit for the list of the antigens present on each bead and the suggested cutoff for estimating

the positive/negative result. The bead is considered positive if two or more of the adjusted values are above the cutoff values. Higher or lower sensitivities can be obtained by adjusting the cutoff.

Note: For LSA MIC, there is only one CalcCON which is defined as the Raw MFI value of the lowest ranked antigen bead.

Calculations for C3d

The Negative Control Sample (*NC*) Raw MFI serves as the Background MFI for C3d calculations

To determine the adjusted value for a bead, subtract the Negative Control sample MFI from the RAW MFI to generate the *BG Adjusted (Background Adjusted MFI Value)* for each individual bead.

Individual Bead MFI - MFI of NC bead = BG Adjusted

Divide the *BG Adjusted* by the MFI of the Calculated Control (CalcCON) of its respective locus to generate the *BCR (Background Corrected Ratio)*. The CalcCON for each locus is the Raw MFI value of the lowest ranked antigen bead for that locus.

BG Adjusted ÷ CalcCON MFI for locus 1= BCR for antigen 'x' from locus 1

BG Adjusted ÷ CalcCON MFI for locus 2= BCR for antigen 'y' from locus 2

BG Adjusted ÷ CalcCON MFI for locus 3= BCR for antigen 'z' from locus 3

To calculate the relative strength (*R Strength*) of an antigen, divide the BG Adjusted values of the individual bead by the corresponding MFI value of the bead in the LSA Negative Control (NC) serum

R Strength = BG Adjusted MFI of Antigen ÷ Raw Value MFI of Antigen in NC

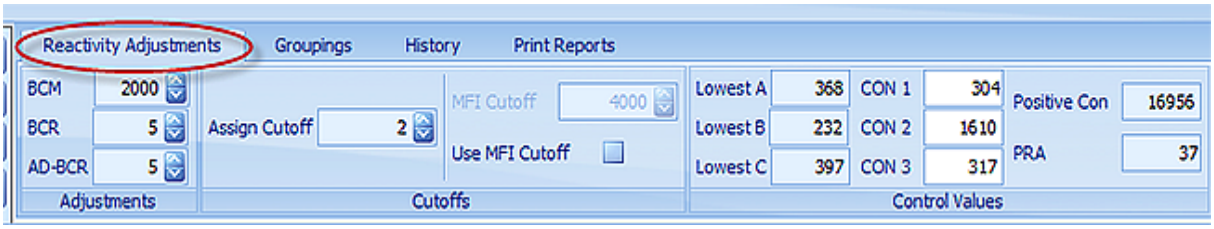
Higher or lower sensitivities can be obtained by adjusting the cutoff.

Making a Positive or Negative Assignment

A bead is assigned as positive or negative based on user defined analysis parameters or by MFI cutoffs. *Weak* assignments are made based on pre-set values that are lot specific.

By Standard Mode (LSA and C3d)

If preferences have not already been set for these parameters or an override is necessary for a particular sample, they can be changed in the *Reactivity Adjustments* tab. *See "Preferences"*

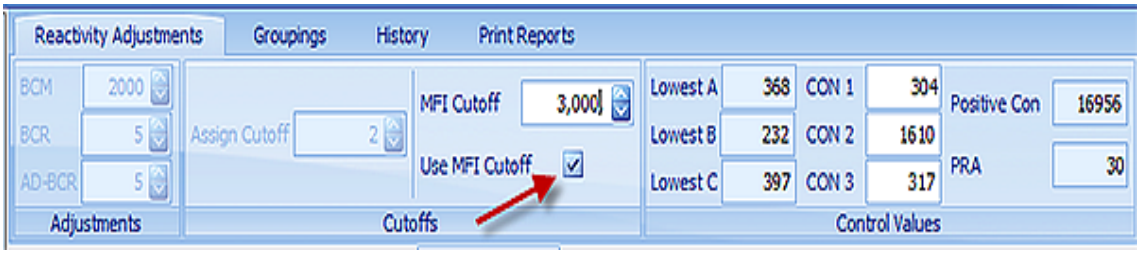


- **Adjustment Values for LSA and C3d (*BCM, BCR, and AD-BCR or BG Adjusted, BCR, and R Strength)*** set the positive threshold for *BCM, BCR, and AD-BCR* (LSA) or *BG Adjusted, BCR, and R Strength (C3d).* Once the value box is selected, the up and down arrows can be clicked to the desired value or a value can also be typed directly into the white box. *The default settings are lot-specific and part of the EDS file used for analysis.*

- **Assign Cutoff (LSA and C3d)** is a score of 1 to 3. It indicates the number of calculations, i.e. *BCM, BCR, and AD-BCR* or *BG Adjusted, BCR, and R Strength* that must be positive for the sample to be assigned as positive. This allows the user to show samples positive with only 1 out of 3 adjustment values positive, 2 out of 3 adjustment values positive, or 3 out of 3 adjustments values. *The default setting is 2.*

By MFI Cutoff (LSA and C3d)

Beads can be assigned as positive or negative by assigning an MFI cutoff. There are three ways to assign an MFI cutoff.



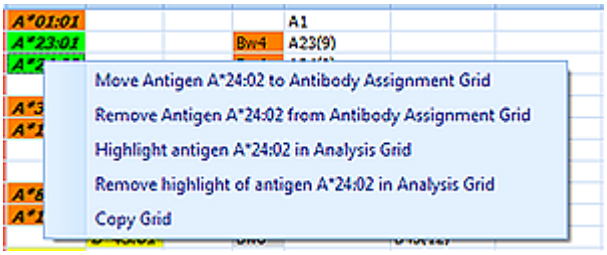
1) Under the *Reactivity and Adjustments* tab, click the box next to Use MFI Cutoff.

2) The *MFI Cutoff* value box is now available. Select the value box. The up and down arrows can be clicked to the desired value or the up and down arrow keys may be used. A value can also be typed directly into the white box. Once the value is entered, click the graph to view the new cutoff.

3) An alternative to step 2 is to right click anywhere on the graph and choose *Graph Edit*. The *Cut Off* bar will then be visible and can be moved to the desired value. Once the cut-off has been set, click **Save**

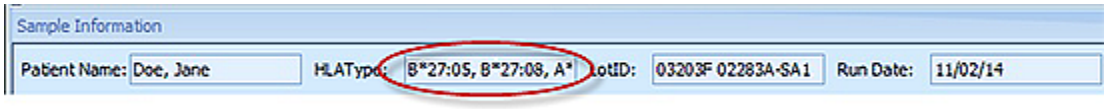
4) To apply an MFI cut-off to all samples for Class I or Class II, a user may select MFI mode in the **LSA or C3d** tab of **Preferences** window. MFI cut-offs can be set individually for Class I and Class II and MICA. The up and down arrow keys may be used. A value can also be typed directly in the white box. The user must then indicate that the value should be applied to data upon import.

Move/Remove/Exclude Antigens to/from the Assignment (LSA and C3d)



•The user may right click an antigen within the assignment grid and choose to **Move** or **Remove Antigens from Antibody Assignments**.

•If **Sample Antigens** were entered into the sample list, they will be displayed in the Sample Information tab.



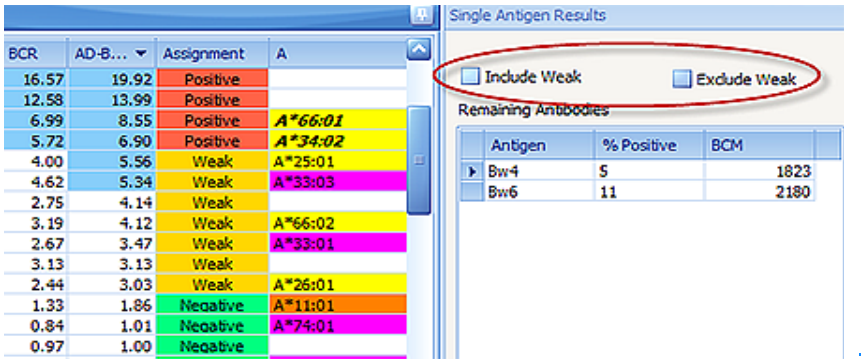
When **Exclude HLA Type** is turned **ON** in the *Reactivity Adjustments* tab (if not already selected under *Preferences*) excluded antigens will be listed under the *Groupings* tab.

•To change the assignment of all *Weak* beads to *Positive* and have all such Antigens listed in *Antibody Assignments*, check **Include Weak** in the *Single Antigen Results* window

•To change the assignment of all *Weak* beads to *Negative*, check **Exclude Weak** in the *Single Antigen Results* window.

Note: Once Include Weak or Exclude Weak is used no changes to the Antibody Assignments can be made

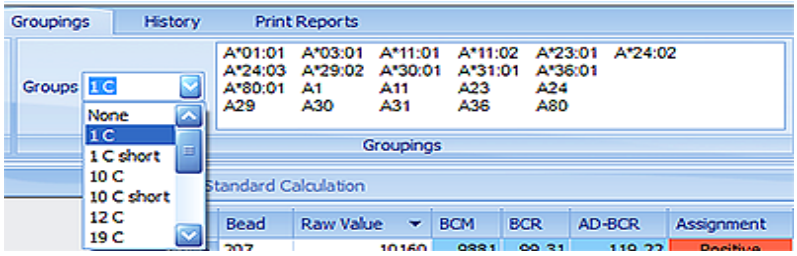
Note: Weak antigens are only assigned for LSA



Tools for Making an Assignment (LSA and C3d)

Groupings

The **Groups** drop-down box is a list of user defined HLA Groups. By selecting a particular group, the antigens present within the particular group will be highlighted. *See "Antibody Reactivity Groups"*

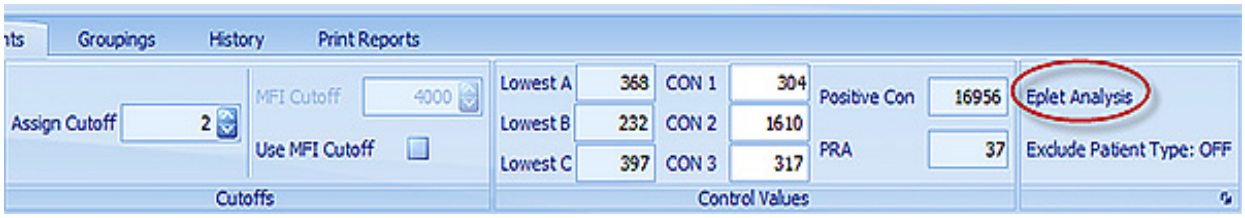


Color-Coded Antigen(s):

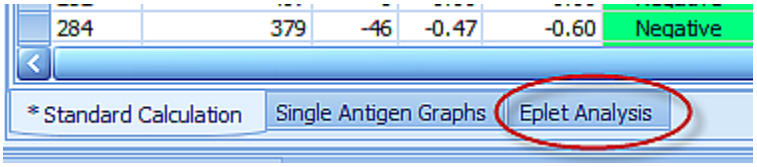
The user can color-code antigens or groups of antigens to provide easier viewing. This feature is intended as a visual aid.

Eplet Analysis

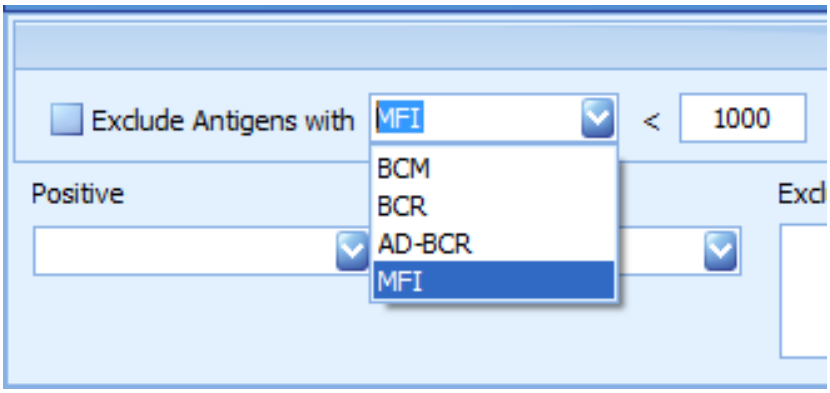
Added Eplet Analysis can be run at a sample level. If epitopes are not calculated upon import click the Eplet Analysis button to assign available epitopes.



Eplets can also calculated in the **Eplet Analysis** tab located at the bottom of the analysis screen.

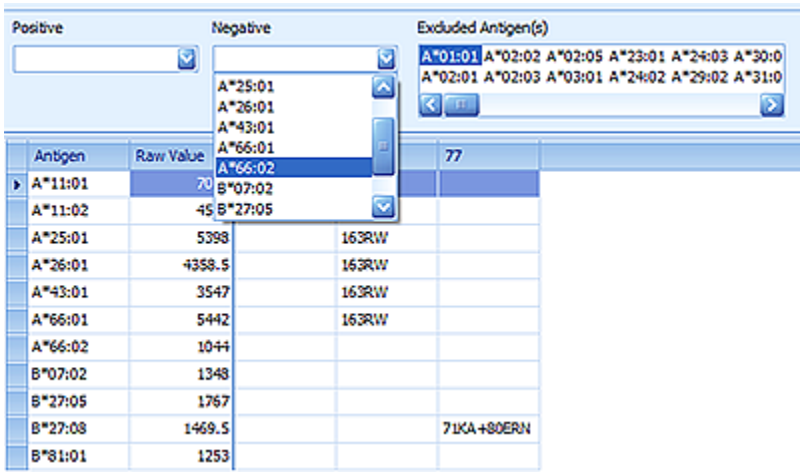


In the Eplet Analysis Tab, the user can refine the list of Eplets displayed by excluding Antigens based on *BCM, BCR, AD-BCR*, or *MFI* values.

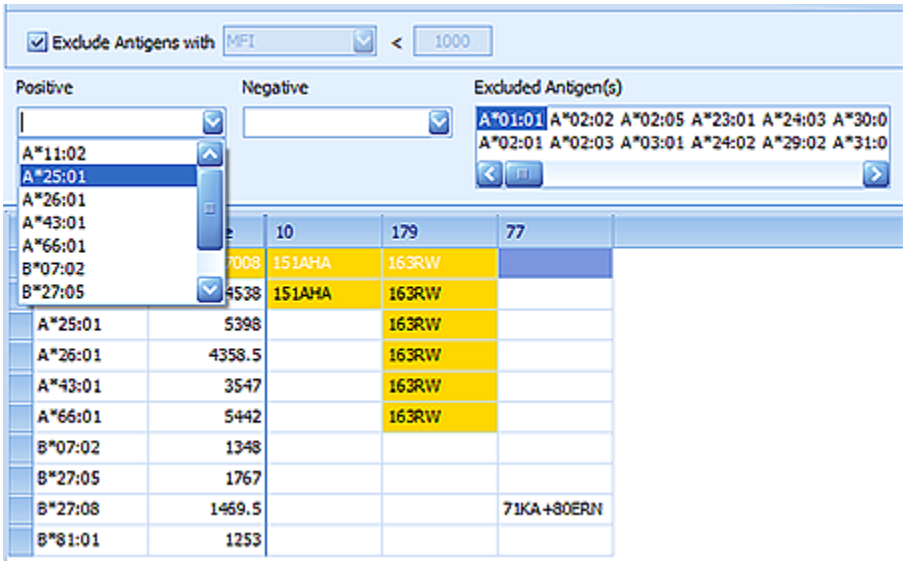


Antigens excluded by these parameters will be listed in the **Excluded Antigens** window.

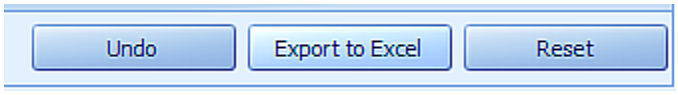
Antigens that are known or predictive Negatives can be selected from the **Negative** drop-down. These Antigens will be removed from the grid and will be added to the **Excluded Antigen(s)** list.



Antigens that are known or predictive Positives can be selected from the **Positive** drop-down list. When an Antigen is assigned as Positive, it will change to bold text and the associated Eplet will be highlighted in the grid.



The user can use the **Undo** and **Reset** buttons at any time during analysis.

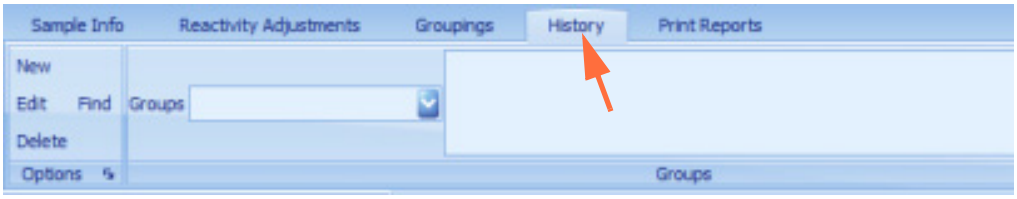


When Analysis is complete the results can be exported to an Excel worksheet using the **Export to Excel** button.

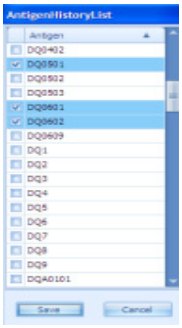
Creating a History (LSA and C3d)

In the *History* tab, a user has the ability to load antigens to create a reactivity group specific to the sample. This will enable a user to create a "snap-shot" for a particular sample and monitor changes in antibody status for a patient across kits and over time.

1) Go to the *History* tab.



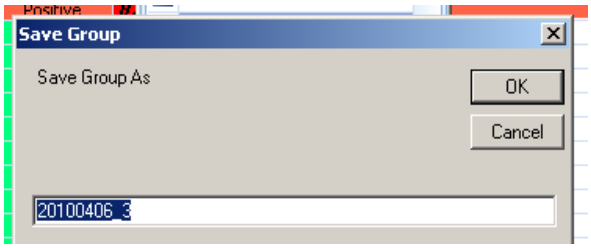
2) Click **New**.



3) The previously assigned antigens (either automatically or manually) will be checked and highlighted in the window which appears. Additional antigens may be added to the history by checking the box next to the antigen *(Note: This will not change the saved assignments)*.

4) Click **Save**.

5) Confirm the decision to make a history snapshot of the results and name the *Antigen History Group*.



Applying a Previously Created History to a New Sample

A previously created History can be viewed with a new sample.

1) Go to the *History* tab of the new sample.

2) Click **Find**.

3) Type either the name of the *Antigen History Group* or a key component of the name, i.e. first letter.

4) The history of the sample will display.

View Current Assigned History for a Sample

1) Go to the *History* tab of the new sample.

2) Select the *History* from the drop-down.

3) The Saved *History Snapshot* will be highlighted.

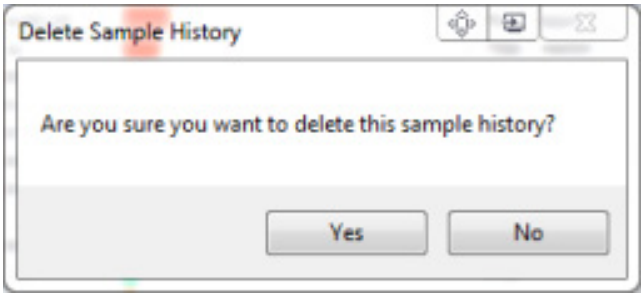
Delete History

1) Go to the *History* tab of the sample.

2) Select a *History* from the dropdown or use Find to search for a *History*.

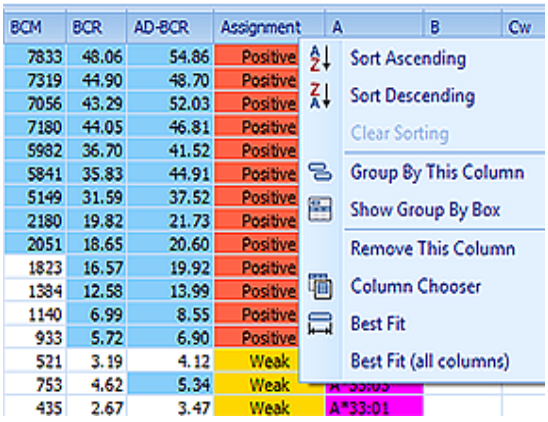
3) The *History Snapshot* will be loaded.

4) Click **Delete,** then confirm deletion.



Column Customization (LSA and C3d)

Columns located in any of the Calculation tabs can be customized to meet the user's needs.



Changing Sort Order

For LSA, samples will display beads in descending order of AD-BCR by default. For C3d samples will display beads. This can be changed two different ways:

1) Right-click a column header and choose *Sort Ascending* or *Sort Descending*. The sort order will be saved when viewing future batches.

2) Left clicking a column header will also sort. Once the column is clicked, a downward or upward triangle will appear showing the direction of order; descending or ascending in value, respectively.

Column Removal/Addition and Column Width

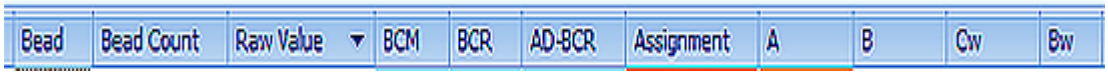
1) To remove a column, right click the column and choose *Remove This Column*.

2) To add a column that has been previously removed, right click the column and choose *Column Chooser*. The **Column Customization** window will appear displaying the columns that have been removed. Right click the column to add and choose *Show This Column*.

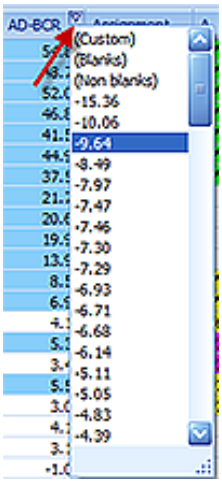
The **Column Customization** window also allows the user to drag and drop columns into the window to customize the layout.

3) To change the width of a column, right click the column and choose *Best Fit* or *Best Fit (all columns)*. The columns will size according to the values in the column and apply it to only that column or to all columns depending on what is chosen.

Displaying Selected Bead Values



Specific beads containing particular information can be viewed.



1) Hover over a column. A small *pin* will appear in the upper right corner of the chosen column.

2) Left click the column header pin. All values or text within that chosen column will be listed.

3) Choose any one of the values or text items displayed. When chosen, only the bead(s) that includes that value or text within that column will display.

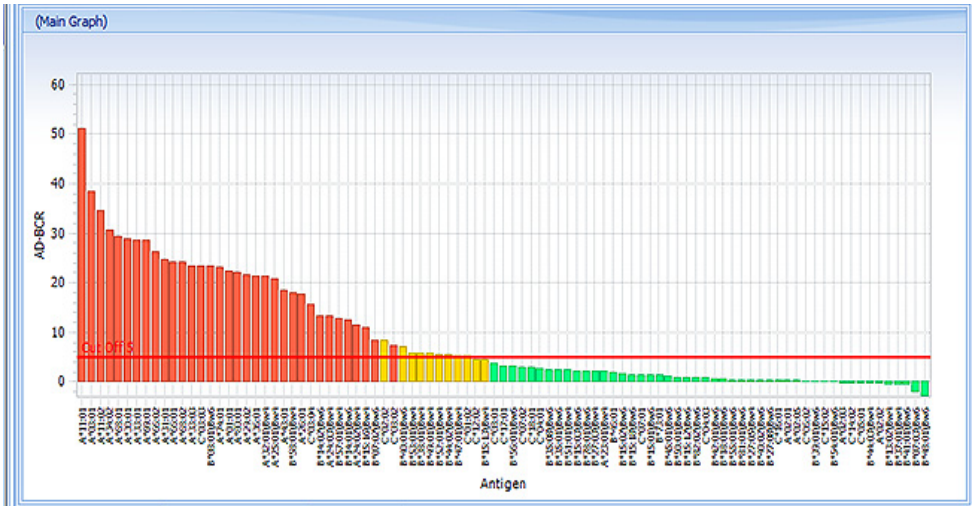
Note: All of the sub-windows and columns may be resized by placing cursor on the line to be moved and dragging the mouse.

Graphical Display (LSA and C3d)

Antigen Graph

A graph of *Raw MFI vs. Bead* enables the user to visualize the strength of each bead relative to the sample and the assignment for each bead; red is a positive assignment, green is a negative assignment, and gold is a weak assignment. There are two views for the graph:

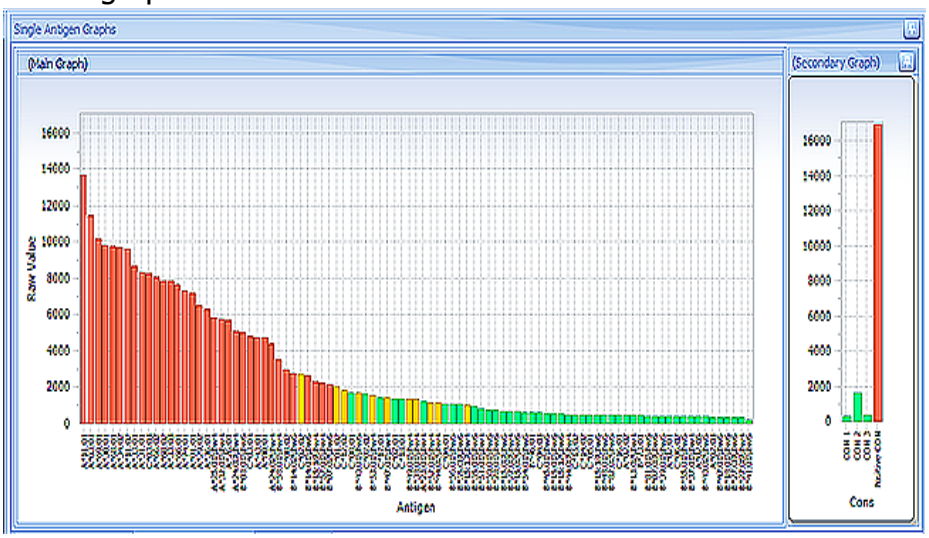
- The **Standard Mode** displays a graph with the positive and negative assignments for beads based on the parameters set *(BCM, BCR, AD-BCR, and Assign Cutoff or BG Adjusted, BCR, and R Strength).* *See "Preferences"*



- The **MFI Cutoff** displays a graph with positive and negative assignments for beads based on the MFI value the user sets as the cutoff.

Control Graph

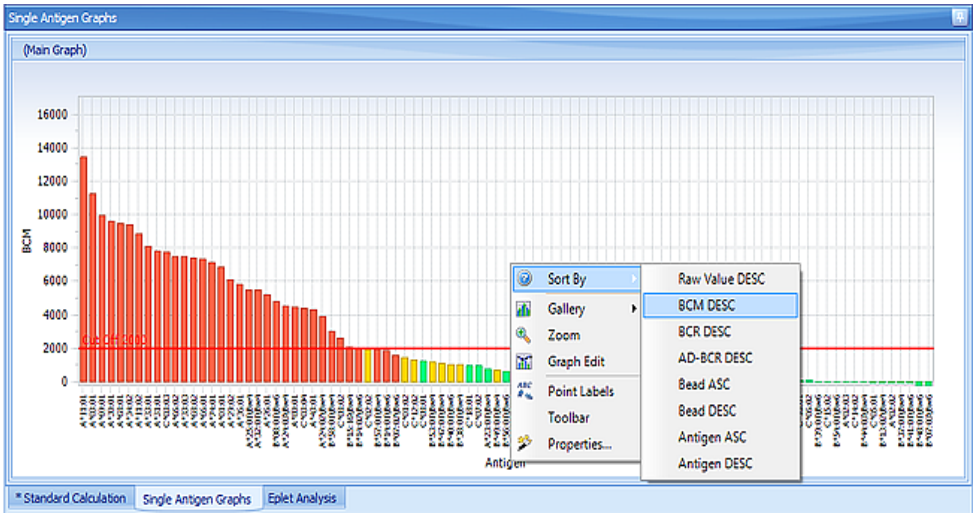
A graph of Raw MFI vs. Controls (Pos and 3 CONS) is displayed next to the Antigen Graph only when *Raw MFI vs. Bead (Antigens)* is chosen as the main graph.



Additional Graphing Features

•To change the y-axis for what is displayed, click any of the column headers; *Raw, BCM, BCR, or AD-BCR or BG Adjusted, BCR, and R Strength*

•To change the bead order (antigen order) of the x-axis, right click anywhere within the graphing area and choose *Sort By*. A selection of antigen sorting options will appear.

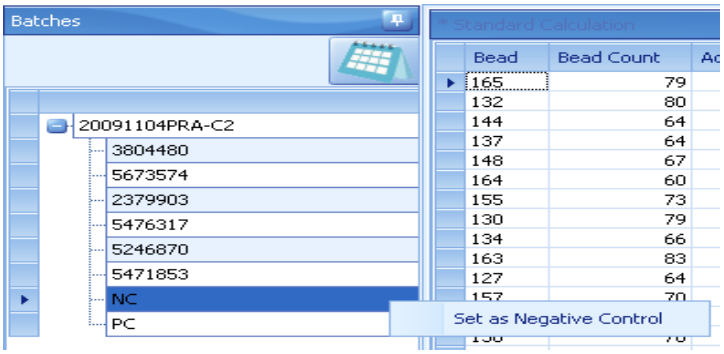


•To change the graph type, i.e. from a bar graph to a line graph, right click anywhere within the graphing area and choose *Gallery*. A selection of graph types will appear.

•To zoom, right click anywhere within the graphing area and choose *Zoom*. Use the mouse to make a box around the area to zoom.

•If a *Group* is selected, the graph will highlight the bars for the beads containing an antigen in the selected *Group*. The gray bars represent beads containing antigens within the selected *Group*.

•To overlay a particular sample; i.e. the negative control, onto each sample graph, select the sample of choice and right click to choose **Set as Negative Control**. Now when viewing any of the sample graphs within the batch, the sample and the set negative control sample will display.



Note: *The user may select one of the samples within the batch to be designated as the Negative Control. Once this option has been turned on for a batch it cannot be turned off. This feature is NOT available for C3d.*

Note: When making reactivity adjustment changes to a sample with ***Weak*** *antigens,* ***Weak*** *Antigens will remain* ***Weak.*** *To change a* ***Weak*** *assignment to* ***Positive,*** *MFI mode must be used.*

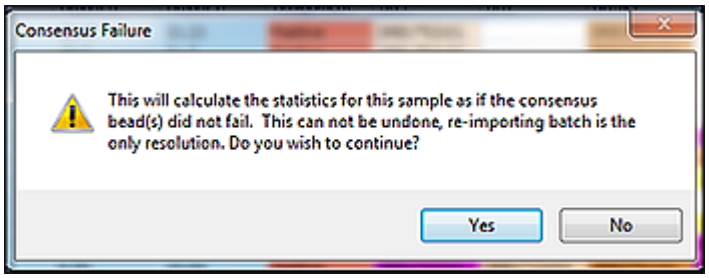
Note: If Eplets are assigned and changes are made to ***Reactivity Adjustments*** *then Eplet assignments will clear. To assign Eplets using the new cut-offs, click* ***Eplet Analysis.***

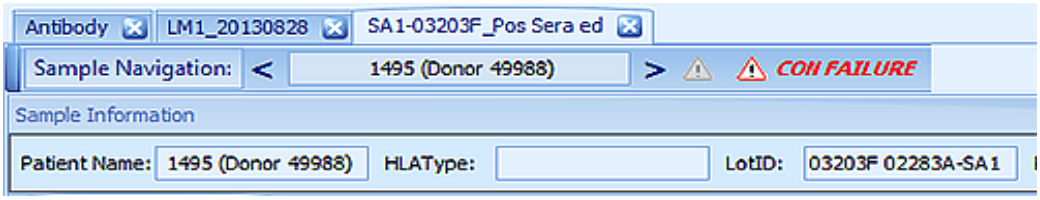
Batch Failures (LSA and C3d)

Bead Count Failure

The source of all failures is listed in the Single Antigen Analysis header. By clicking the *FAILED* message, the user has the option to included failed beads in the analysis.

- If a CON bead fails to meet the minimum bead count, the software will report all beads as failed. To override the failure, click the message. A message box will appear to confirm the override.


Consensus Failure
This will calculate the statistics for this sample as if the consensus bead(s) did not fail. This can not be undone, re-importing batch is the only resolution. Do you wish to continue?
Yes
No



-

•If a sample fails to meet the minimum bead count for a particular result, the bead will be flagged as *FAILED*. To override the failure, double click the message and select the failed beads to include in the analysis.

Note: If a sample has both CON failures AND bead failures, the CON failure must be overidden before the failed beads can be included.

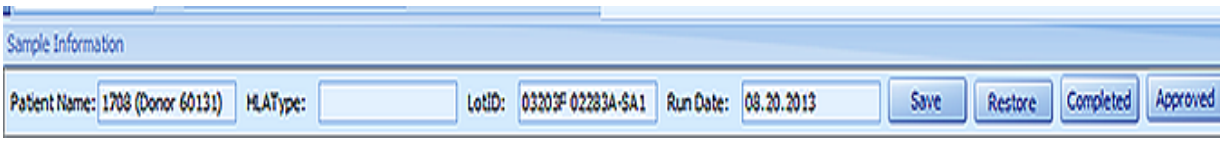
Approving the Results of the Analysis

Saving Results

When **Save** is clicked, the analysis for the sample is saved but can be analyzed again.

When **Restore** is clicked, the sample will revert to the most recently saved data/assignments.

Once analysis is complete and no additional changes need to be made for a particular sample, click **Completed**. Only a *Technician* or *Lab Supervisor* may make changes to a sample by clicking **Completed** again. Once all samples in a batch have been completed, the batch will be listed as **Completed** on the home page and signify they are ready for sign-off**.**



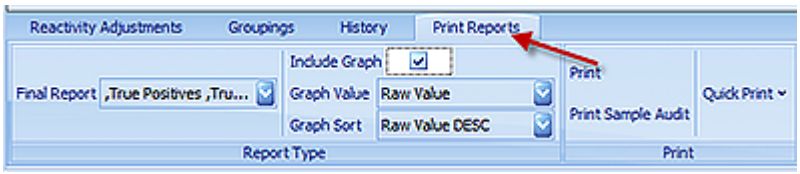
Once the analysis of completed results has been reviewed, click **Approved**. Once clicked, changes can no longer be made except by a *Lab Supervisor* by clicking **Approved** again. Approving results will list the batch as **Approved** on the home page.

Reporting and Printing

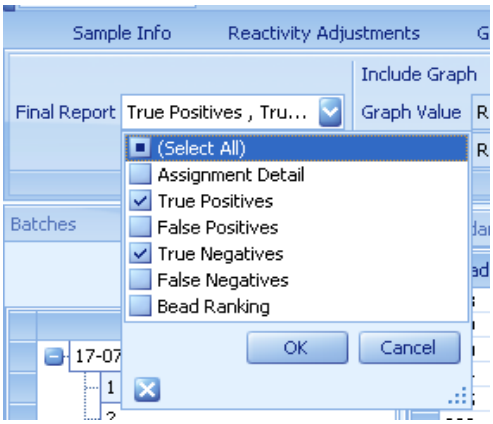
After the sample has been analyzed, (automatically or manually) the user has the ability to customize a report.

Customizing a Final Report

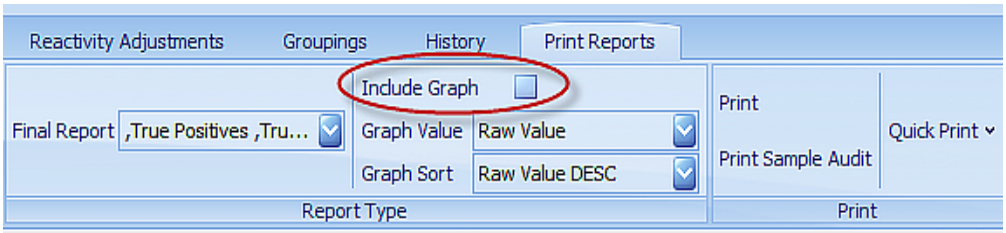
1) Once the results for a sample have been *Approved*, go to *Print Reports* tab.



2) Click the drop down arrow next to *Final Report* and select the items to include in the Final Report.



3) A graph can be included in the report as well by checking the box next to *Include Graph*. *Graph Value* (y-axis) and *Graph Sort* (x-axis) may also be customized by clicking the drop down arrow and selecting the appropriate choice.



3) Once a report appears on the screen, click the *Print* icon in the upper toolbar.

Quick Print

Either a Bead Ranking report or Graph can be printed by clicking Quick Print.

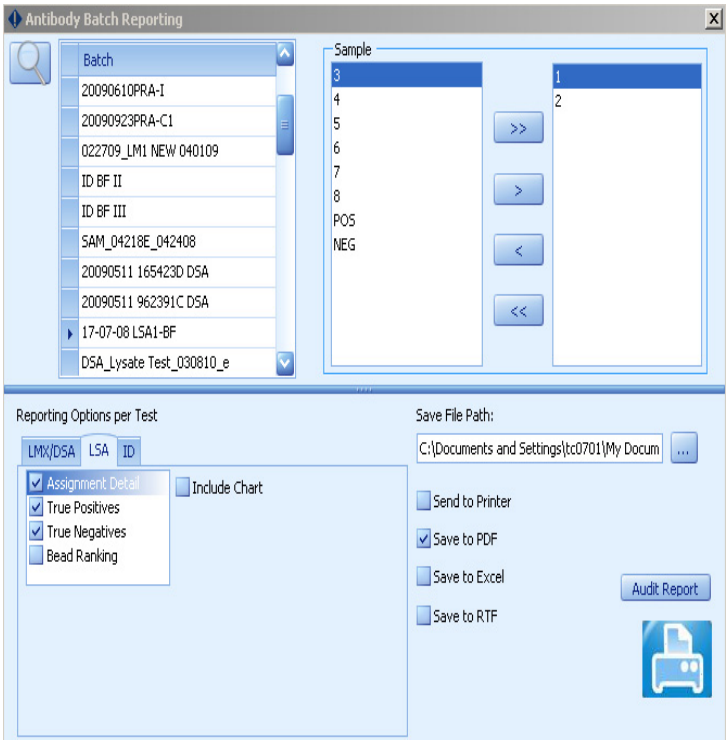
The **Bead Ranking Report** is sorted as it is sorted in the grid. All antigens associated with each bead will be listed, as well as whether the bead was assigned as **Positive** or **Negative**.

Batch Reporting

1) Go to the *Home Antibody* Tab.

2) Click the *Antibody* icon.

3) Click the magnifying glass to display a calendar.



4) Choose the date or range of dates of when the batch was imported.

5) Batches will display in the *Batch* column. Double click the batch of choice. All samples within the batch will display in the *Sample* column.

6) Use the arrows to move the samples to the *Print (right)* column which will include them in the batch reporting.

7) Once all desired samples have been

moved to the *Print (right)* column, choose the LSA tab in the **Reporting Options**. Choose the items to include in the report.

8) Select desired **Printing Option**: *Send to Printer, Save to PDF, Save to Excel,* or *Save to RTF*. Multiple options may be chosen. If *Save to PDF, Save to Excel,* or *Save to RTF* is chosen choose a *Save File Path*.

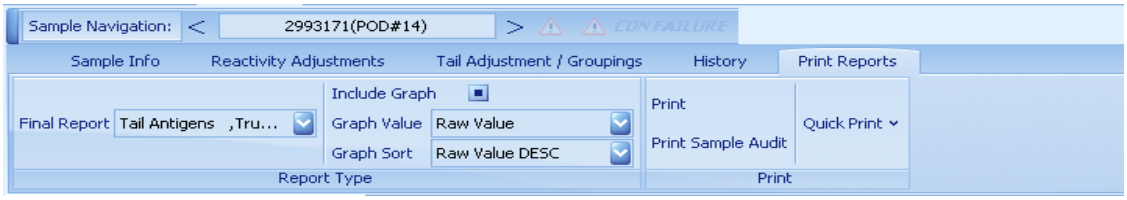
9) Click the *Print* icon. A dialogue box will appear stating that reports have been generated. Click **OK** to continue.

10) If an *Audit Report* is desired, click **Audit Report**. This report can only be generated in pdf format.

Exporting Reports

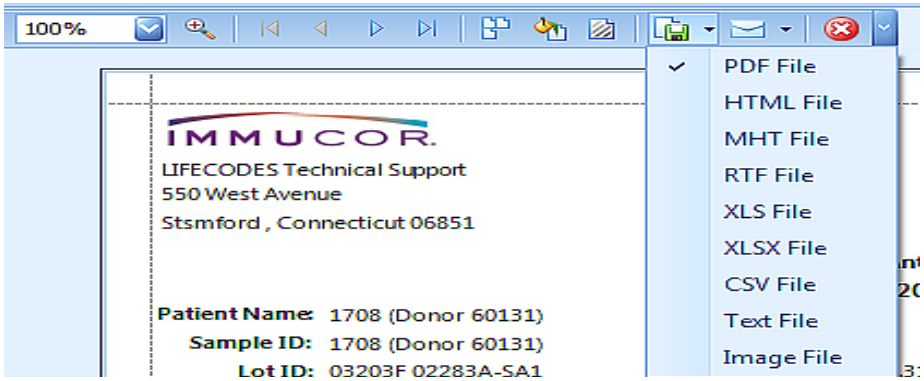
(PDF, HTML, MHT, RTF, Excel, CSV, txt, or Image File)

1) Generate a report from the *Print Reports* tab in the *LSA Analysis* tab.



2) Once a report appears on the screen, click the **Export Report** icon in the upper right toolbar.

3) The dialog box that appears provides several different options for exporting/saving the report.



Exporting Summary Results

Many Laboratory Information Systems require simple export files that list only the samples and results. This file can be generated directly from the *Export* tab. *See "Export Results"* .

CHAPTER 7: DSA ANALYSIS

This chapter contains information on the tools available to analyze LIFE-CODES Donor Specific Antigen results (DSA).

Importing DSA Results into MATCH IT!

If an Automated Batch was not created and data needs to be manually imported into the software, the appropriate EDS file must first be imported followed by the csv file.

Importing EDS files

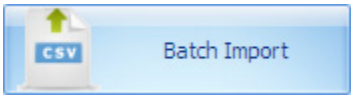
Before importing DSA data, the information necessary for analyzing the data generated by the Luminex instrument must be imported. The information is provided in lot-specific EDS files.

1) Click **Lot Information Import** found on the Home tab of MATCH IT!. The Open dialog box will appear.

2) Navigate to the location, e.g., desktop, of the EDS file(s). Select all appropriate files that need to be imported. Use Ctrl + left mouse button to select more than one EDS file at one time.

3) Click **Open**. A message will appear when all lots have been successfully imported.

Manually Importing CSV Files



1) Click **Batch Import** from the homepage. This will open the *Open* dialog box

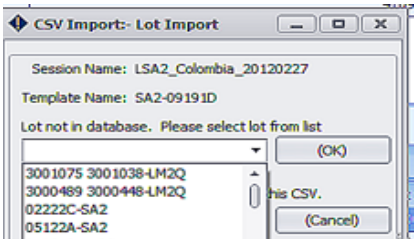
2) Navigate to the location of the CSV file(s). If importing from the computer connected to the Luminex, CSV files can be found in C:\My Batches\Outputon IS 2.3 systems and at C:\ProgramData\Luminex\xPONENT31\Output on xPONENT systems.

3) Select all CSV files to be imported. Use Ctrl + left mouse button to select more than one CSV file at one time.

4) When the file is selected, the analysis is done automatically during the import process. Once the csv file has been imported, it will appear on the Antibody Home tab under DSA.

Note: *A* ***CSV Import: Lot Import*** *may appear after selecting a csv file. This can be due to:1) the appropriate EDS file not being imported, 2) the*

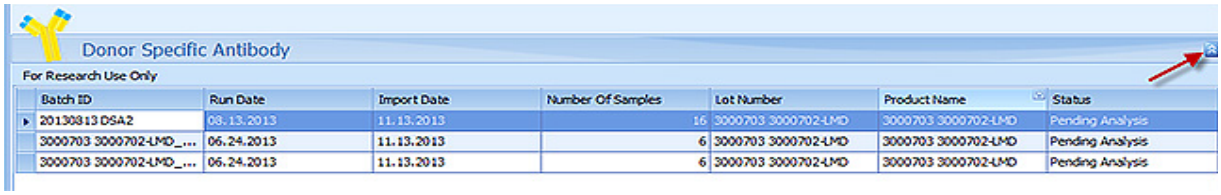
EDS file not being available *See "Lot Availability"* *, or 3) the lot number not being indicated on the CSV file.*



Opening a Batch

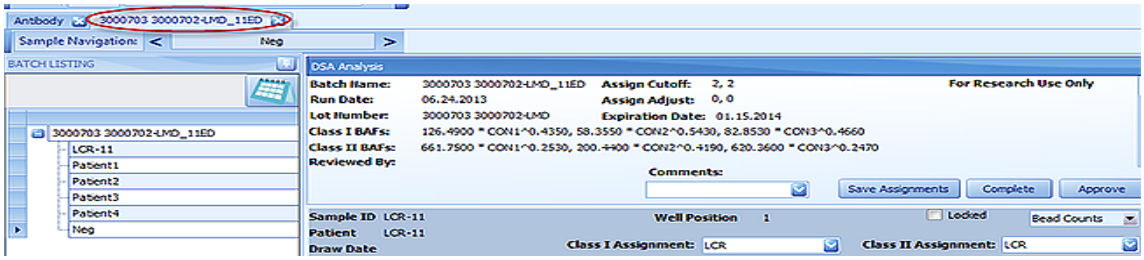
Direct Selection

1) Click the arrow to first expand the *DSA* section.



2) Double click the batch name found on the Antibody Home tab under *DSA*.

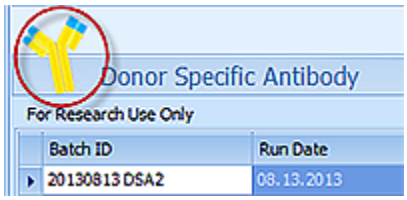
3) The batch results are displayed in a tab above the sample navigation ribbon. All sample results appear in the middle section of the tab. Individual sample IDs within the selected panel are listed in the left section of the tab under the batch name.



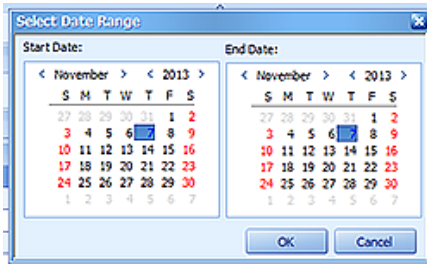
Date Range Selection

Rather than selecting an individual batch, a range of dates can be selected, which will result in all batches run in that range being selected.

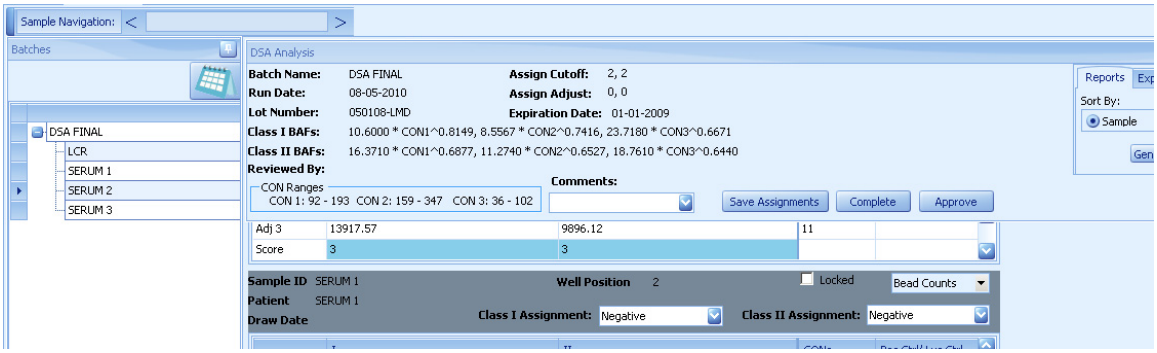
1) Right click the antibody symbol as shown below.



2) A pair of calendars with a start and end date will open. Select the desired range and click OK.



3) The batch results are displayed in a tab above the sample navigation ribbon. All sample results appear in the middle section of the tab. Individual sample IDs within the selected panel are listed in the left section of the tab under the batch name.



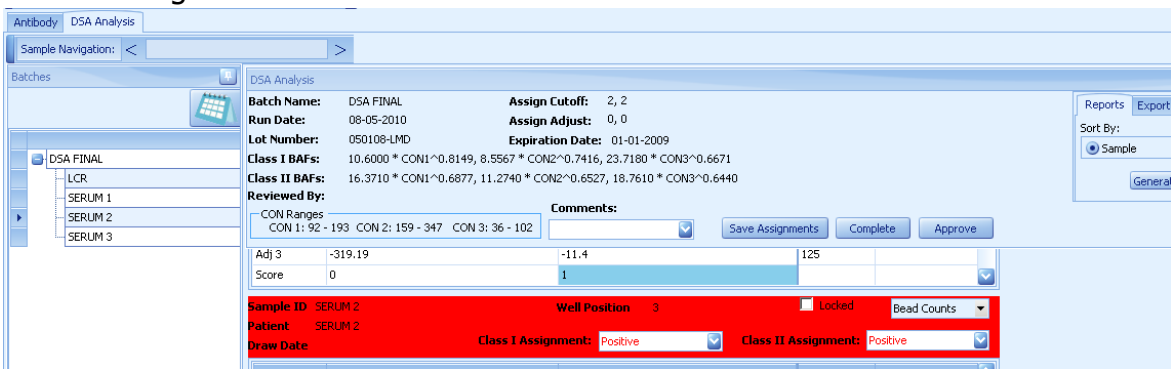
Viewing and Changing the Results of a Batch

Scrolling through a Batch

If all of the data for the batch does not appear on the screen, the scroll bar can be used to move among the different samples.

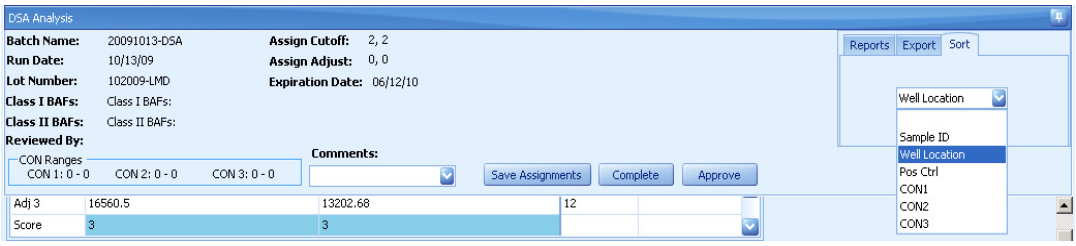
Navigating to a Particular Sample

To go to a particular sample in the batch, left click the sample name in the left hand pane. The software will jump to this sample and it will be highlighted in red.



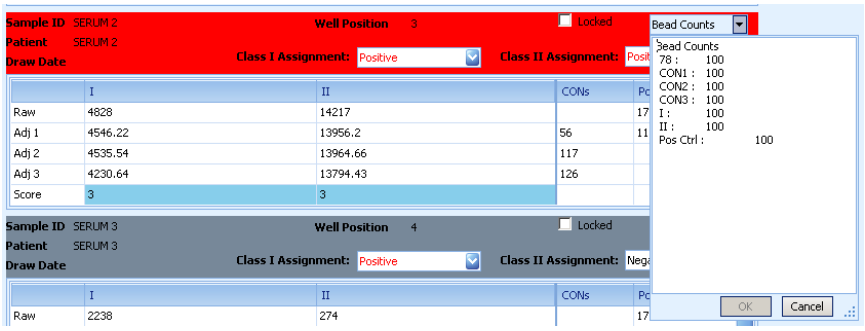
Changing the Sort Order

The samples within a batch are loaded in order of their location in the batch. By selecting the Sort tab located in the upper right, the results can be ordered by *Sample ID*, *Well Location* (default), *CON1, CON2, CON3, Pos ctrl,* or *Lys Ctrl Bead*.



Displaying Bead Counts

To display the bead counts for a sample, click the down arrow next to *Bead* in the sample header.



Assignments, Displayed Values and Calculations

Bead Assignment

To determine the adjusted values for a capture bead, the MFI value of each capture bead is compared to three cutoff values (background adjustment factors; BAFs). The three cutoff values are calculated from the background measured on the three CON beads in each test well. Each CON bead has an equation for calculating the cutoff value for the Class I HLA capture bead and a separate equation for calculating the cutoff value for the Class II HLA capture bead. The two equations for each CON bead are lot-specific and can be found on the Recording Sheet. The cutoff value calculated for a CON bead is subtracted from the MFI value of the capture bead. The process is repeated for each of the remaining two CON beads to obtain three results (Adjusted MFI Values).

Example: *Class I HLA BAF for CON1* $= 49.465(CON1)^{0.5312}$

Class I HLA BAF for CON2 $= 34.622(CON2)^{0.5673}$

Class I HLA BAF for CON3 $= 29.615(CON3)^{0.6532}$

Example: *Class I HLA Capture Bead MFI - (BAF for CON1) = Adjusted MFI 1*

Class I HLA Capture Bead MFI - (BAF for CON2) = Adjusted MFI 2

Class I HLA Capture Bead MFI - (BAF for CON3) = Adjusted MFI 3

Class Assignment

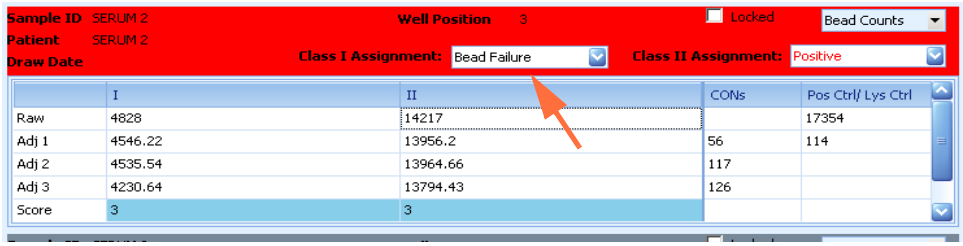
•A sample is considered positive for donor specific antibodies if two or more adjusted MFI values are positive.

•A sample is considered negative for donor specific antibodies if two or more adjusted MFI values are negative. *See "Preferences"*

Batch Failures

Bead Count Failure

•If a sample fails to meet the minimum bead count for a Class I or Class II bead, the Class I or Class II result, respectively, will be reported as bead failure. To override the failure, review the bead count and then choose the appropriate assignment from the drop-down menu.



•If a CON bead fails to meet the minimum bead count, the software will report bead failure for both Class I and Class II.

Positive or Negative Control Failure

•A Negative Control is considered as failed if any bead fails to meet the minimum bead count, or if the Negative Control has a positive assignment for Class I or Class II.

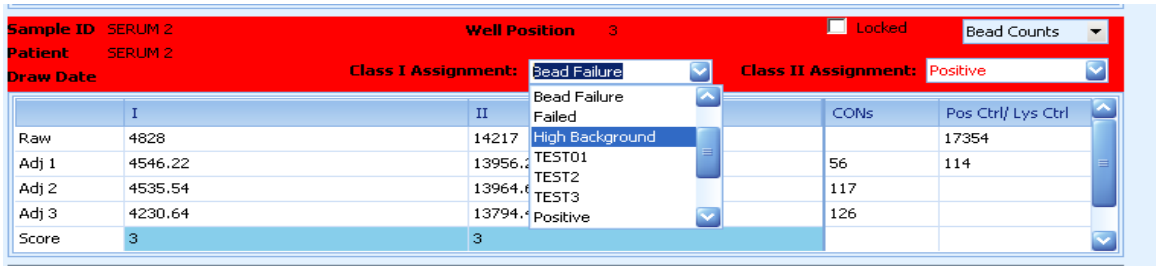
•A Positive Control is considered as failed if any bead fails to meet the minimum bead count, or if either of the Class I or Class II assignment is negative.

The source of the failure is listed in the *DSA Header*.

Overriding an Assignment

While the software performs analysis according to the product insert, all results should be reviewed. During this review process, an assignment can

be changed manually by clicking the arrow on the right side of the text box and selecting one of the choices that appears.



Overriding Default Parameters

The default parameters *(Assign Adjust and Assign Cutoff)* should only be altered by personnel knowledgeable in the field of HLA Antibody Analysis. Changing these values will result in altered specificity and sensitivity of the assay. See also for details on changing parameters.

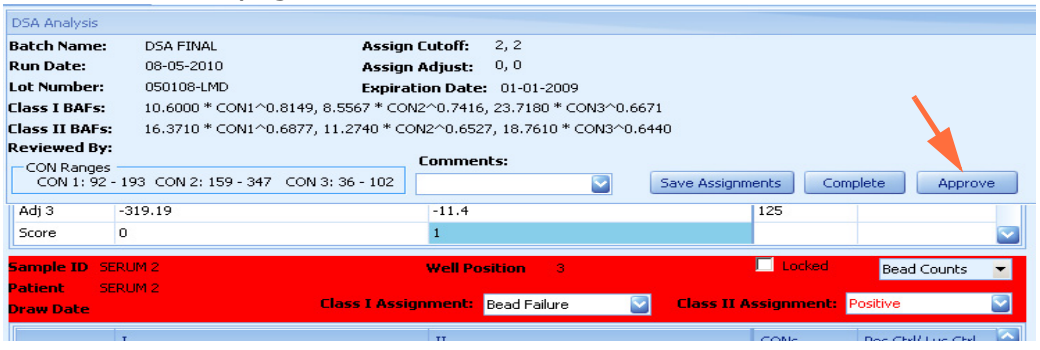
Approving the Results of the Analysis

Saving, Completing, and Approving an Assignment

The **Save Assignments** button saves any assignment edits that have been made. Changes can be made and re-saved.

The **Complete** button locks all the samples in the batch and signifies all samples have been analyzed and are ready for sign off. When a batch has been completed and locked, only a *Lab Technician* or *Lab Supervisor* may unlock the samples by clicking **Complete** again. Completing the results lists the batch as *Completed* on the home page.

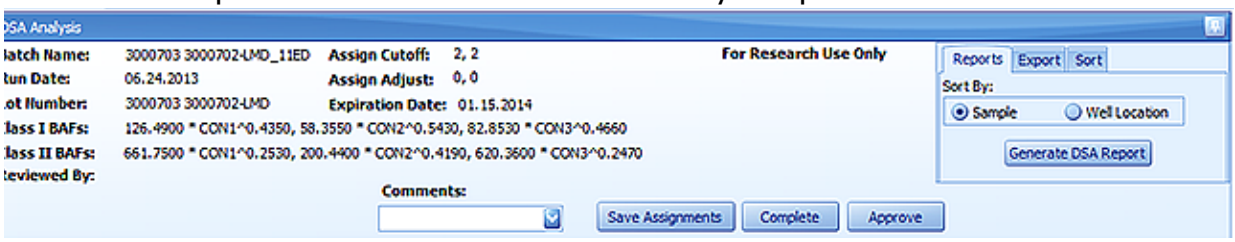
The **Approve** button signified the samples are finished. When a batch has been approved, only a *Lab Supervisor* may unapprove the samples by clicking **Approve** again. Approving the results lists the batch as *Approved* on the home page.


DSA Analysis
Batch Name: DSA FINAL
Run Date: 08-05-2010
Lot Number: 050108-LMD
Class I BAFs: 10.6000 * CON1^0.8149, 8.5567 * CON2^0.7416, 23.7180 * CON3^0.6671
Class II BAFs: 16.3710 * CON1^0.6877, 11.2740 * CON2^0.6527, 18.7610 * CON3^0.6440
Reviewed By:
Assign Cutoff: 2, 2
Assign Adjust: 0, 0
Expiration Date: 01-01-2009
CON Ranges
CON 1: 92 - 193 CON 2: 159 - 347 CON 3: 36 - 102
Comments:
Save Assignments
Complete
Approve
Adj 3 -319.19 -11.4 125
Score 0 1
Sample ID SERUM 2
Patient SERUM 2
Draw Date
Well Position 3
Locked
Bead Counts
Class I Assignment: Bead Failure
Class II Assignment: Positive

Reports

Printing Standard Report

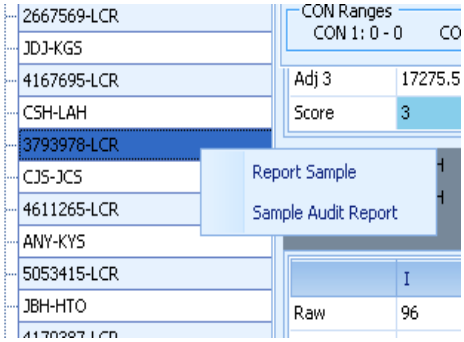
1) Once the results have been accepted, a report can be generated. The report for the batch can be ordered by sample or well location.



2) The report is created by pressing the **Generate DSA Report** button.

3) Once a report appears on the screen, click the *Print* icon in the upper toolbar.

Printing an Individual Sample Report or Audit Report



1) Select the sample ID in the *Batch Listing* pane.

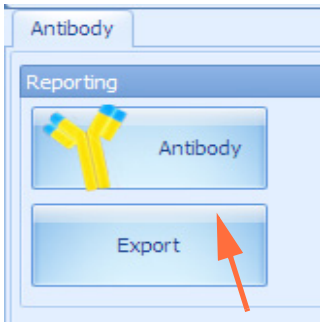
2) Right click the sample ID to access the report options: *Report Sample* or *Sample Audit Report.* A *Sample Audit Report* will only be generated if changes to the sample have been made. If no changes then no report will appear.

3) Once a report appears on the screen, click the **Print** icon in the upper toolbar.

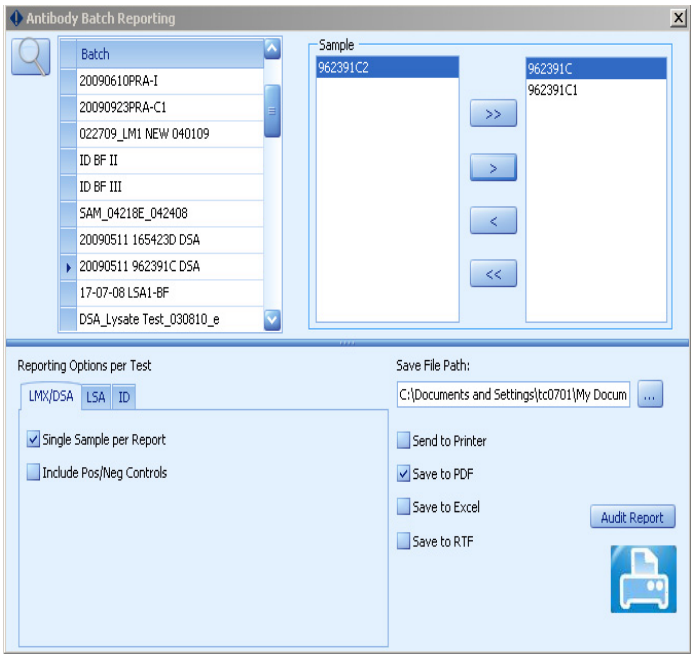
Batch Reporting

1) Go to the *Home Antibody* tab.

2) Click the *Antibody* icon.



3) Click the magnifying glass to display a calendar.



4) Choose the date or range of dates of when the batch was imported.

5) Batches will display in the *Batch* column. Double click the batch of choice. All samples within the batch will display in the *Sample* colunmn.

6) Use the arrows to move the samples to the *Print (right)* column which will include them in the batch report.

7) If individual reports of the samples moved to the *Print (right)* column are preferred, choose the LifeScreen/DSA tab under **Reporting Options** and check *Single Sample per Report*. There is then the option to *Include Pos/Neg Controls*.

8) Select desired **Reporting Option**: *Send to Printer, Save to PDF, Save to Excel,* or *Save to RTF*. Multiple options may be chosen. If *Save to PDF*, *Save to Excel*, or *Save to RTF* is chosen, choose a *Save File Path*.

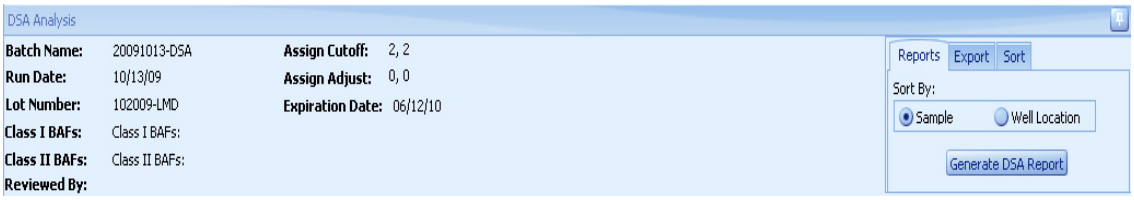
9) Click the *Print icon*. Either one report containing all chosen samples will be generated or individual reports for each chosen sample will be generated.

10) If an *Audit Report* is desired, click **Audit Report**. This report can only be in pdf format.

Exporting Reports

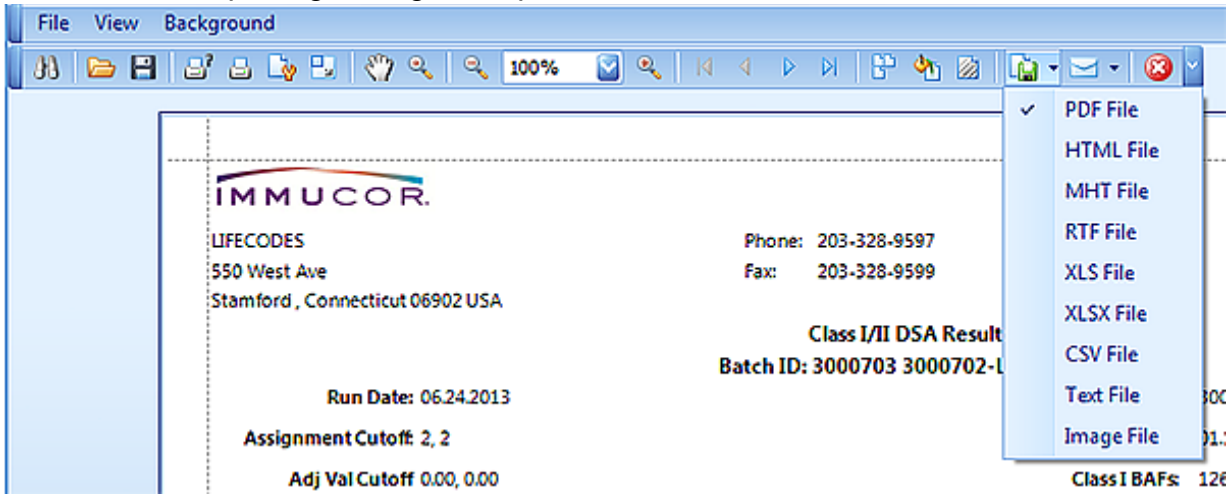
(PDF, HTML, MHT, RTF, Excel, CSV, txt, or Image File)

1) Generate a report from the *Reports* tab in the *DSA Analysis* tab.



2) Once a report appears on the screen, click the **Export Report** icon in the upper right toolbar.

3) The dialog box that appears provides several different options for exporting/saving the report..



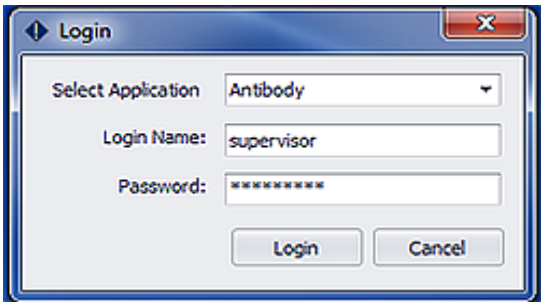
Exporting Summary Results

Many Laboratory Information Systems require simple export files that list only the samples and results. This file can be generated directly from the *Export* tab. *See "Export Results"* .

Chapter 8: Database management

This chapter provides information regarding managing databases; including creating, deleting, backing up and storing databases.

To open the database management window you must first click on the **Start** button located at the lower left of the computer screen.



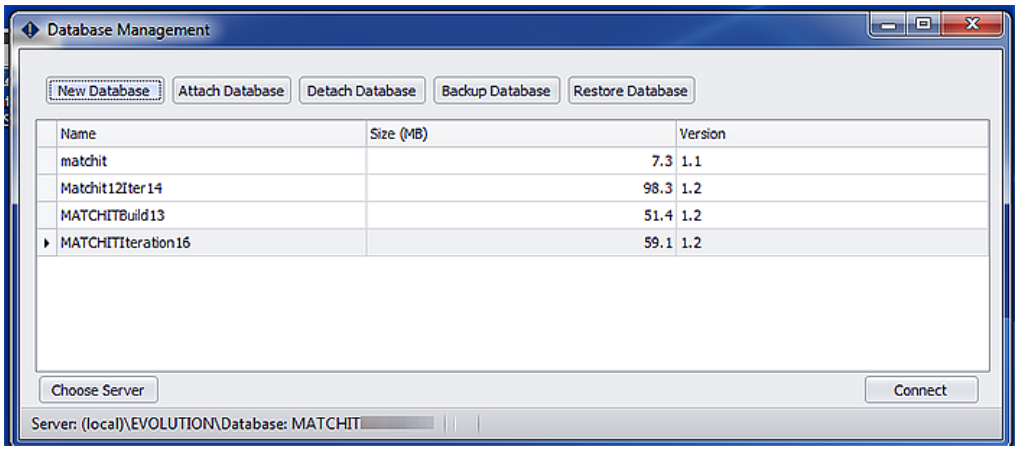
1) Go to **All Programs** and then select **Lifecodes.**

2) Select **Database Management** .

3) Select *Antibody* from the **Application** dropdown.

4) Sign in using the same *Login* and *Password* that are used to access the Matchit! Antibody analysis software (*Login*: supervisor, *Password*: lifecodes) and click **Login.**

5) The **Database Management** window will open.



Creating a New Database

To create a new database, select **New Database**. A prompt for a name will appear. A database name must start with a letter. Once named, click Ok.

Deleting a Database

To delete a database, highlight the database to be deleted and select **Delete Database**. A prompt will appear asking if the database should be deleted. Select **Yes** to delete the database. Once a database is deleted, it cannot be retrieved and all data is lost.

If the current database in use needs to be deleted, the user must connect to another database by highlighting and clicking **Connect** or create a new database and connect to it. Once a new connection has been established, the former database in use can be deleted.

Attaching a Database

To attach a database, select **Attach Database.** A dialog box will appear where the user selects the database to be attached. This feature is only available on the PC housing the database.

Detaching a Database

Detaching a database removes it from the server list, but does not delete the database. It can be attached later if needed. To detach a database, highlight the database and select **Detach Database**. The database that is currently in use cannot be detached. This feature is only available on the PC housing the database.

Backing Up a Database

To backup a database, select **Backup Database**. Next, navigate to the location where the backup is to be kept.

If the software is running on Windows 7, Backup files should be stored at C:\ProgramData\Lifecodes\Backup.

If the software is running on Windows XP Backup files should be stored at C:\Documents and Settings\All Users\Application Data\Lifecodes\Backup.

Restoring a Database

To restore a database, select **Restore Database**. Next, select the location where the backup to be restored is kept.

If the software is running on Windows 7, Backup files should be stored at C:\ProgramData\Lifecodes\Backup.

If the software is running on Windows XP Backup files should be stored at C:\Documents and Settings\All Users\Application Data\Lifecodes\Backup.

This feature is only available on the PC housing the database.

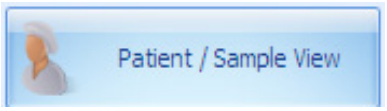
Choosing a Server

In order to connect to a SQL database on another computer, select **Choose Server**. From here, the SQL Instance and database can be selected. If the SQL instance does not appear in the drop down, it can be entered manually.

Connecting to a Database

To choose the database to be used, first highlight the database and then select **Connect.**

Chapter 9: Sample View

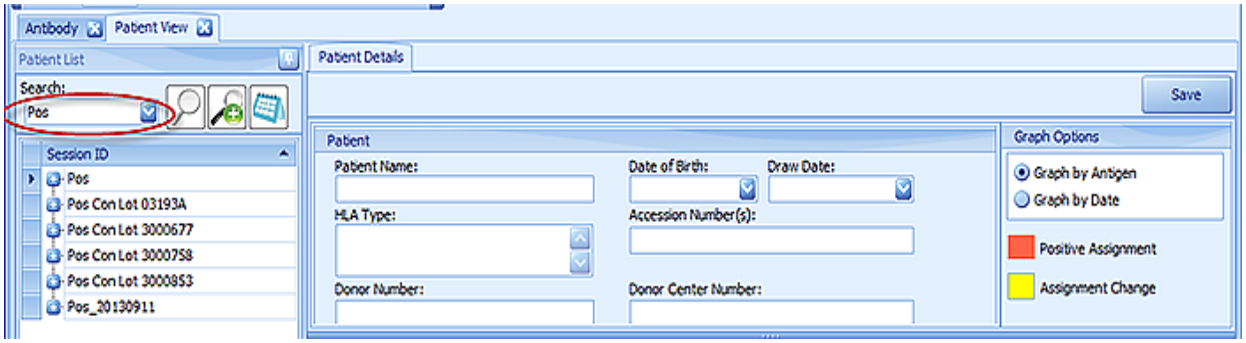


This chapter contains information regarding viewing data for a particular sample. All batches can be displayed, graphically compared from one batch to another, and antibody history viewed.

Sample Search

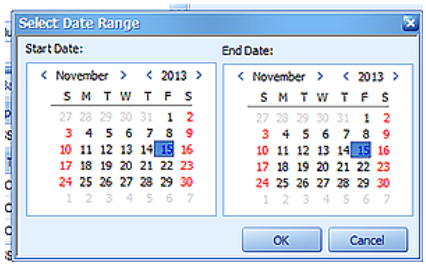
By Sample ID Name

Type the sample ID or sample name into the search box and click the magnifying glass. As the ID is typed into the box, the auto-complete feature will activate. All batches containing that sample ID will display. Click the batch for it to appear in *Antibody Batch Results*.



By Run Date

Click the calendar and choose a range of dates or specific date. All samples from batches run within the range or date will display. Click the batch for it to appear in *Antibody Batch Results*.



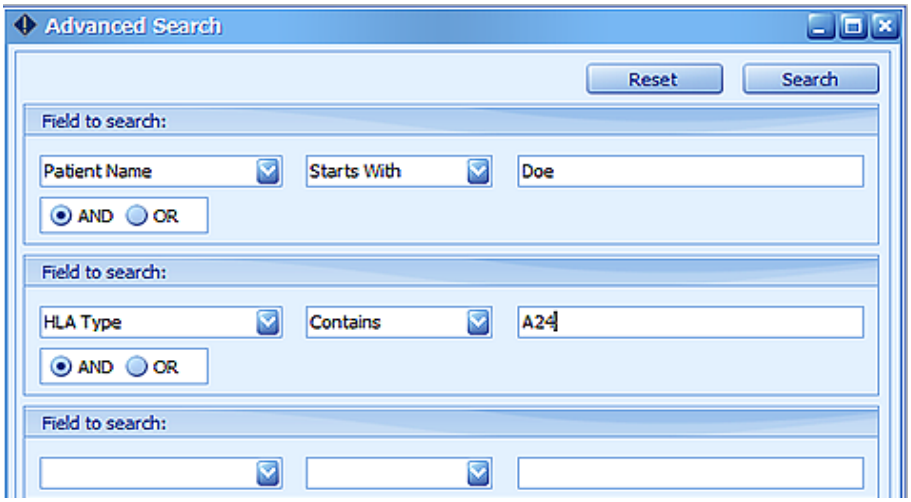
Advanced Sample Search

Selecting the Advanced Sample Search button will allow the user to search for samples by multiple identifiers.

To Use this feature, first select the **Advanced Search** button from the Advanced Search Window. Then click the first drop-down to search by Assignment, Patient Name, Donor Center, Donor Number, or HLA Type.

Select the appropriate qualifier (Equals, Starts With, Contains) from the second drop-down.

Enter the specific search term in the window. Up to three fields can be included in a single search.



Once all desired fields have been chosen, click **Search.**

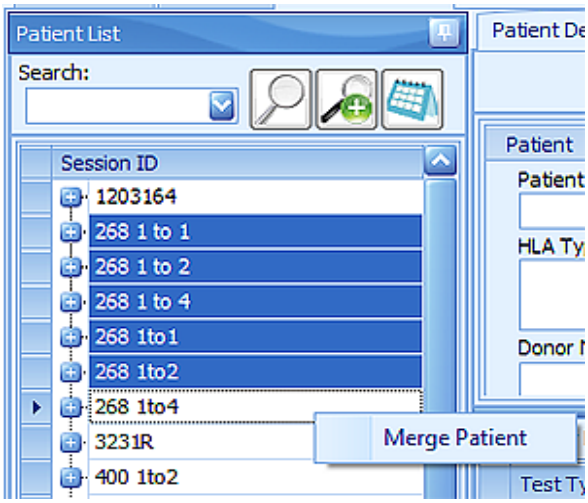
All Samples that fulfill the search requirements will be listed on the left under **Patient List.**

Merge Sample IDs/Sample Names

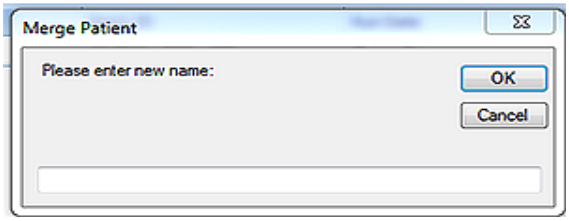
1) To merge sample IDs or sample names, first find the sample ID or sample name by searching by date.

2) Highlight the first ID. Hold the Ctrl key as the other IDs are selected.

Once all IDs are highlighted, right click and choose *Merge Patient*.



3) Name the new Sample.

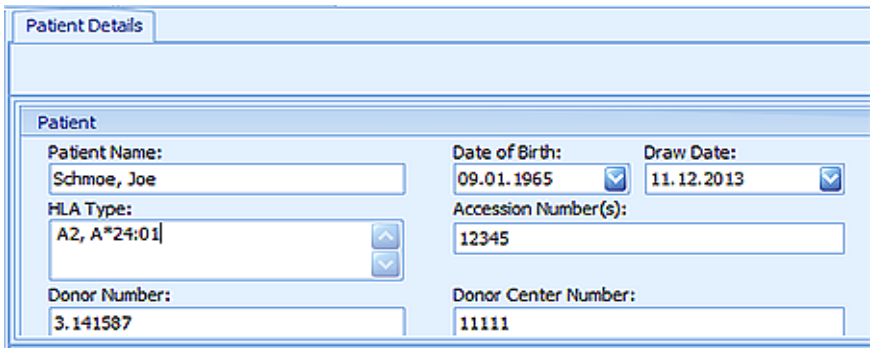


Now the sample ID or sample name can be found as they were originally named as well as found under the new merged name.

Viewing Antibody Batch Results

Patient Information

If Patient Name, Date of Birth, Draw Date, HLA Type, Accesstion Number, Donor Number, or Donor Center Number were included in the auto-batch set-up, they will be displayed in the *Patient Details* tab of **Patient View** for each individual sample.



The user can also manually enter this data in to any one of these fields.

Manually Entering Patient Data

1.Select the batch from the Patient List window.

2. Enter the Patient Details.

3. Click *Save.*

Note: The user will be prompted to save Patient Details for the single batch or for all batches containing the sample. If the user chooses to save for All Batches, the draw date, if entered, will be applied only to the selected batch.

Entering HLA Type

Patient HLA Type can be is manually entered in the **Patient Details** tab. Once saved it will display in *Patient Information* in the Analysis screen and on reports generated for that sample.

If a user wants to *Exclude* the patient HLA type then antigens entered into this field must match an antigen listed on a product worksheet and be separated by commas.

Example:

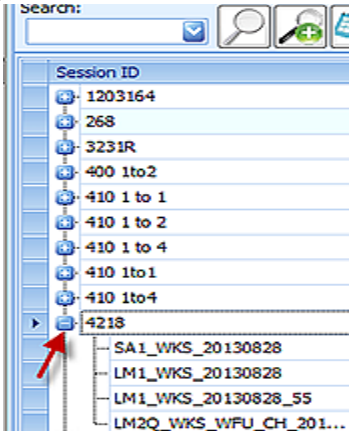
A2, A24, B56, B51

or

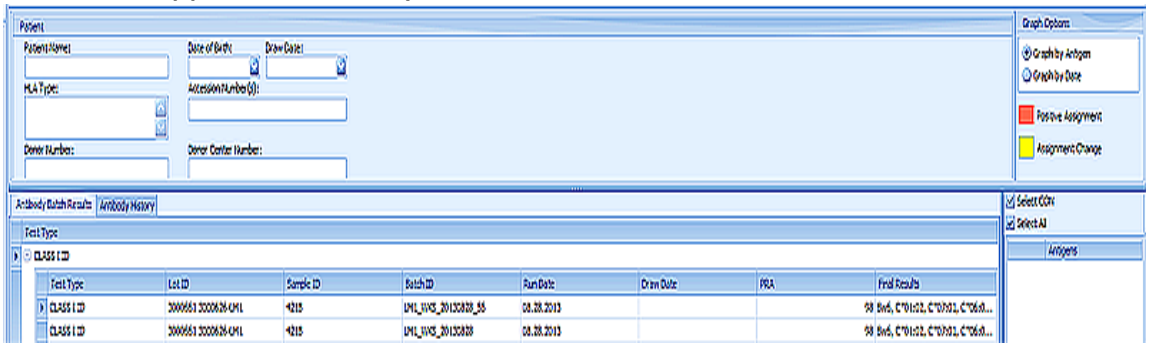
A*02:01, A*24:02, B*56:01, B*51:01

Displaying Batches (

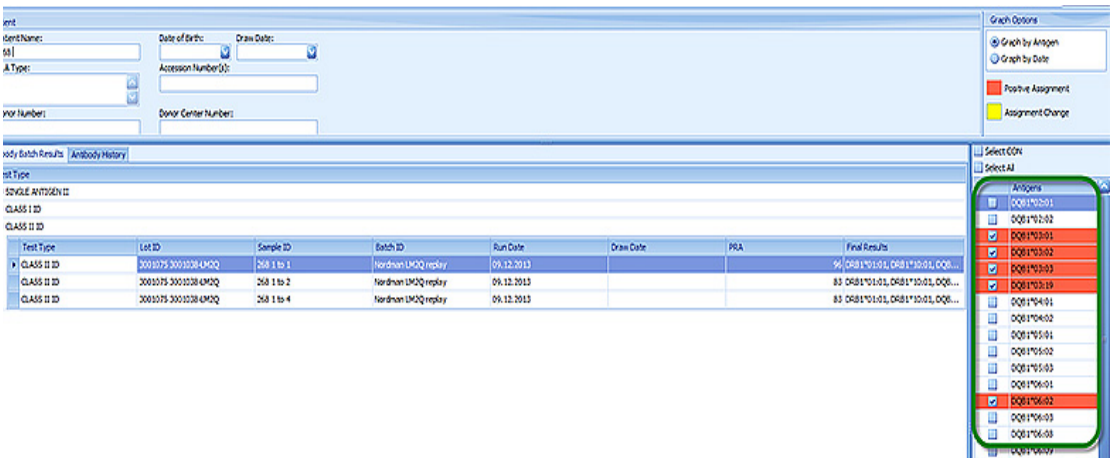
1) To view all batches containing a specific sample, double-click the sample name or click the **+** icon. All batches containing that sample will display under the *Antibody Batch Results* tab.



2) Click any of the batches listed for the selected sample for all results to appear in *Antibody Batch Results*.



3) The antigen specificities for the chosen batch will display once the batch is selected.



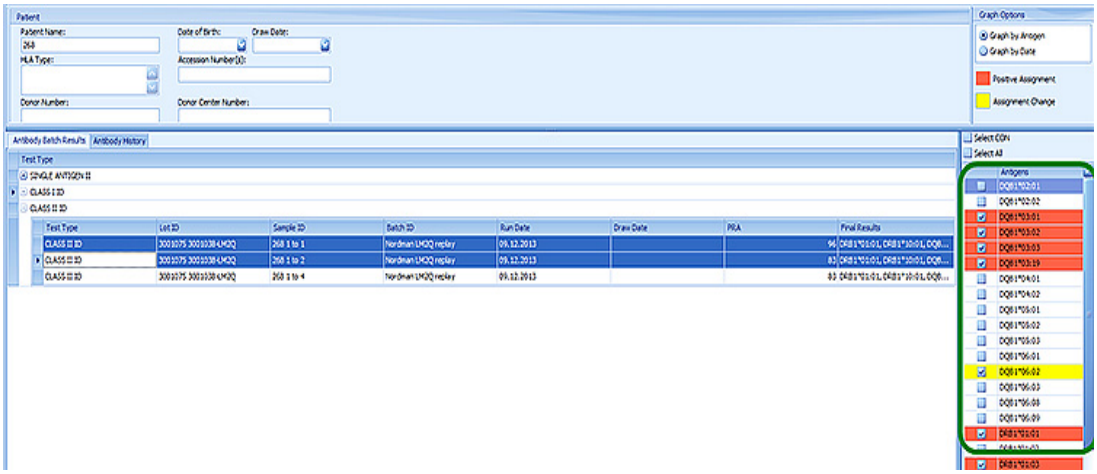
*Note: C3d batches will display in **bold** type*.

If two batches have been run for a chosen assay and both batches are selected by holding down the ctrl key, any differences of antigen assignments between the batches will be highlighted.

Red and Checked Antigens are Positive in all batches.

Red and Un-checked Antigens are Negative in the first batch and Positive in the Positive in the second batch.

Yellow and Checked Antigens are Positive in the First batch and Negative in the Second Batch.



Note: Double click the batch to get to the original analysis tab.

3) If an *Antibody History* was created previously for a particular sample, the history will display in the *Antibody History* tab. Edits to the history can be made here as well.

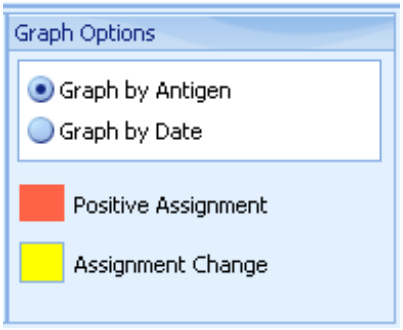
See "Creating a History" for LMID

See "" for LMSA

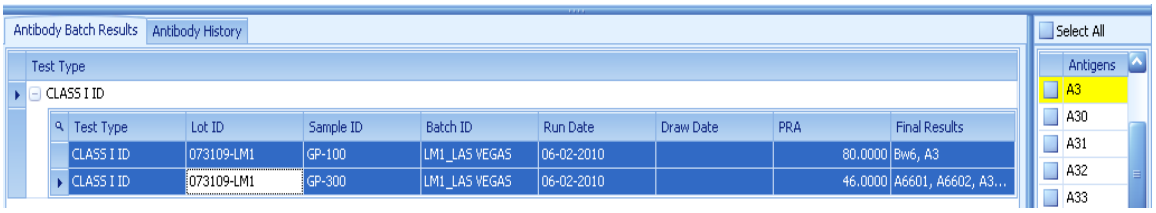
Graphing Antigens across Several Batches for LSA and ID

A graph can be created with combined results from multiple batches.

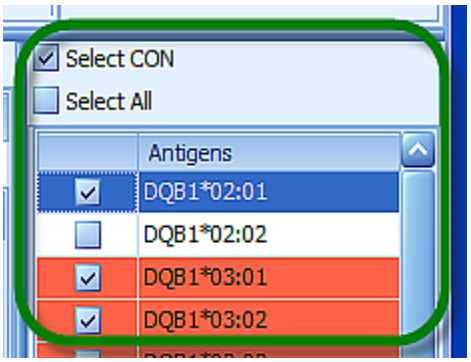
1) Choose to either **Graph by Antigen** or **Graph by Date**.



2) Go to the *Antibody Batch Results*. Hold the ctrl key while selecting each batch to be included in the graph.

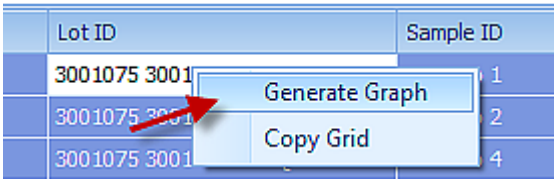

Antibody Batch Results
Antibody History
Select All
Test Type
CLASS I ID
Antigens
A3
A30
A31
A32
A33
Test Type | Lot ID | Sample ID | Batch ID | Run Date | Draw Date | PRA | Final Results
CLASS I ID | 073109-LM1 | GP-100 | LM1_LAS VEGAS | 06-02-2010 | | 80.0000 | Bw6, A3
CLASS I ID | 073109-LM1 | GP-300 | LM1_LAS VEGAS | 06-02-2010 | | 46.0000 | A6601, A6602, A3...

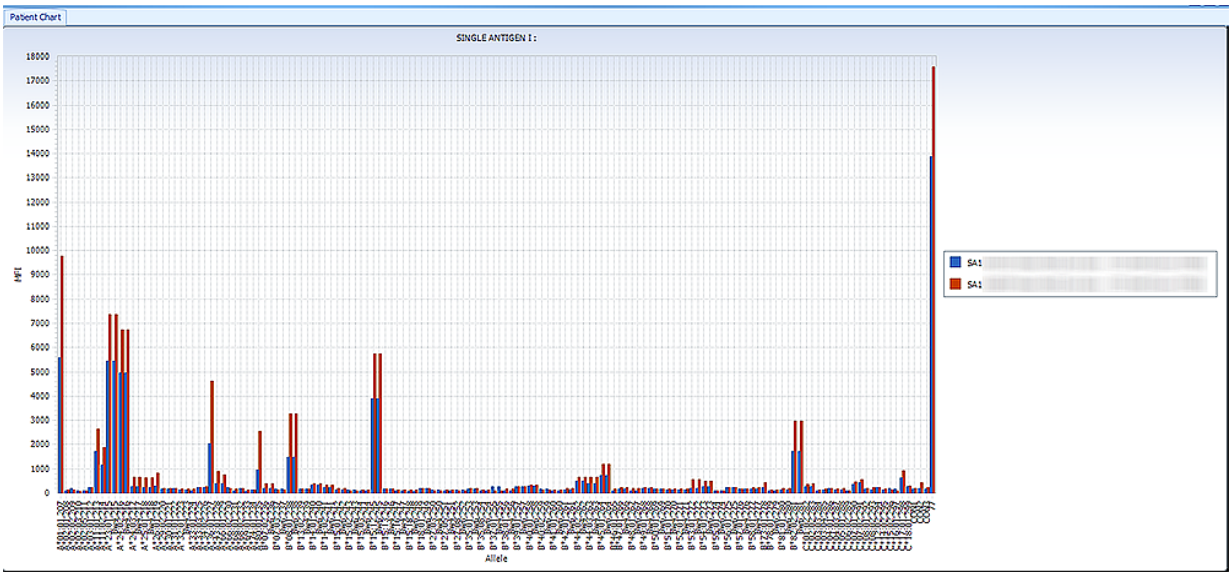
3) Assigned antigens to be graphed will appear in the *Antigen* column on the right. Differences in assignments between the two panels will be highlighted in Yellow. Additional antigens can by added by selecting manually



4) To include the CON value in the graph mark the box for *CON*. To include all Antigens in a graph mark the box for *Select All .*

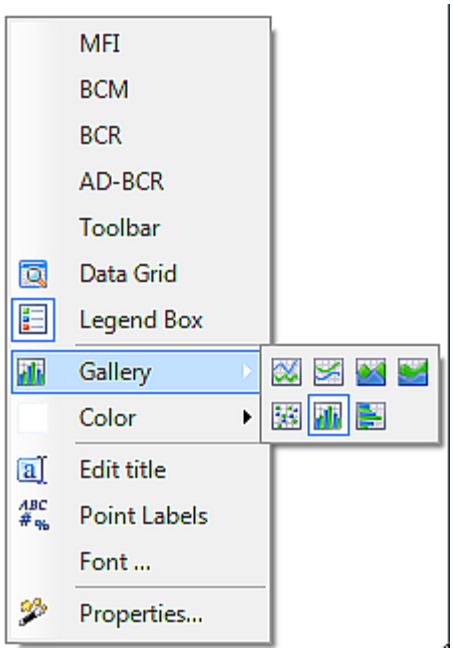
5) Right click the highlighted batches and choose *Generate Graph*.





By default the graph will be a bar graph with Antigens listed on the X-axis and MFI on the y-axis.

To modify the style of graph or to graph by an assay-specific calculated value (ADJ1, BCM, etc) right click anywhere in the graph and select from the menu that appears.

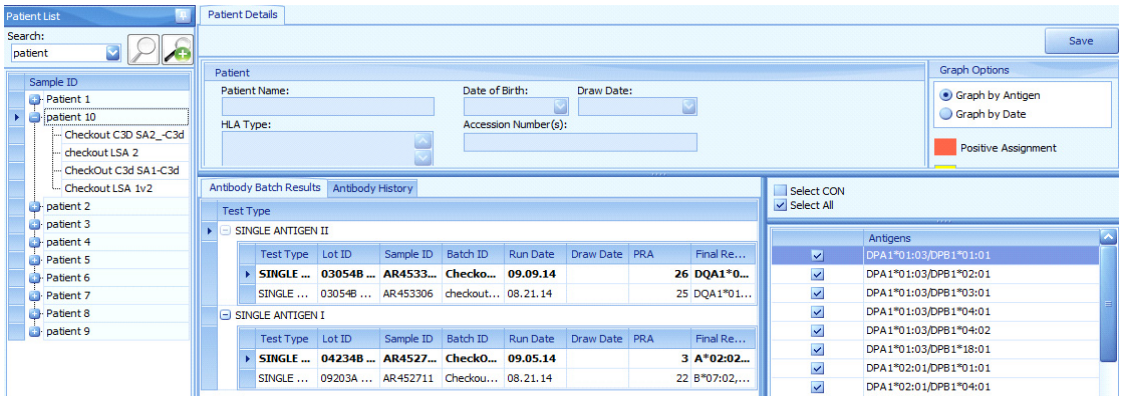


Creating Paired data sets and Graphing LSA IgG and C3d

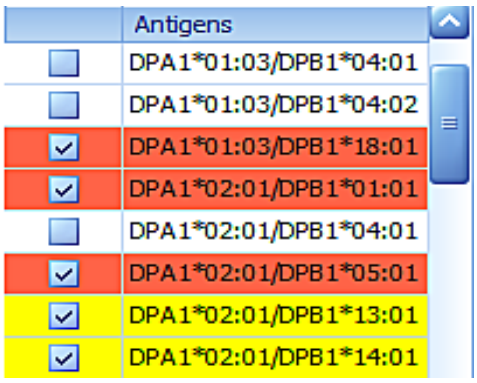
Creating LSA IgG-C3d paired data sets

1) Search for the sample by name or by run date in the Patient List Search Window

2)Click any of the batches listed for the selected sample for all results to appear in *Antibody Batch Results*. C3d batches will display in bold type.

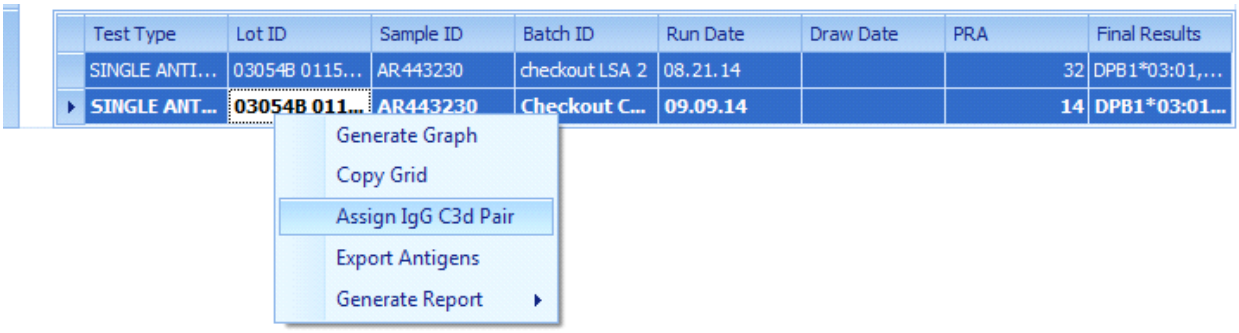


3) Selecting an individual batch will display the assigned antigens for that batch in the antigen column on the right. The user can select an LSA IgG batch and a C3d batch by holding down the **CTRL** key when the second batch is selected. Differences in assignment between the two batches will display in yellow. Additional antigens can be selected manually.



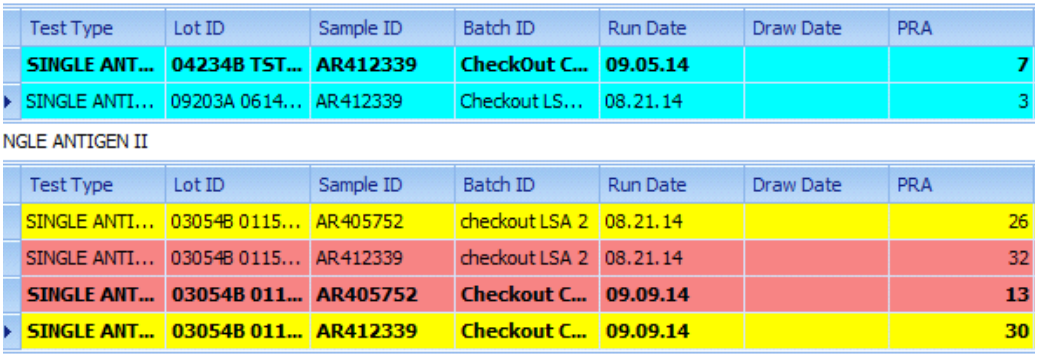
4) Data from LSA IgG and C3d must be paired to generate an LSA-C3d combined report.

a) Select the data set to be paired from the batches listed. Hold down the CTRL key to highlight both LSA and the C3d. As batches are selected they will be highlighted in blue.



b) Right-click and select **Assign IgG-C3d Pair** from the pop-up.

c) Assigned pairs will be highlighted. The first assigned pair for a sample will be highlighted in light blue. The second assigned pair for a sample will be highlighted in red. Any subsequent paired data sets will be highlighted in yellow.

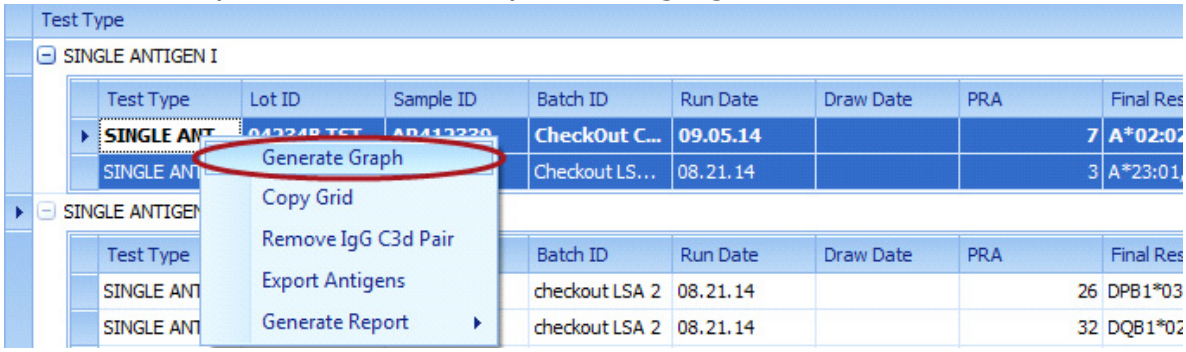


Note: IgG-C3d pairs must be assigned in order to use the ***Export IgG-C3d pair*** *function in* ***Exports/Reports.***

Graphing LSA IgG -C3d paired data

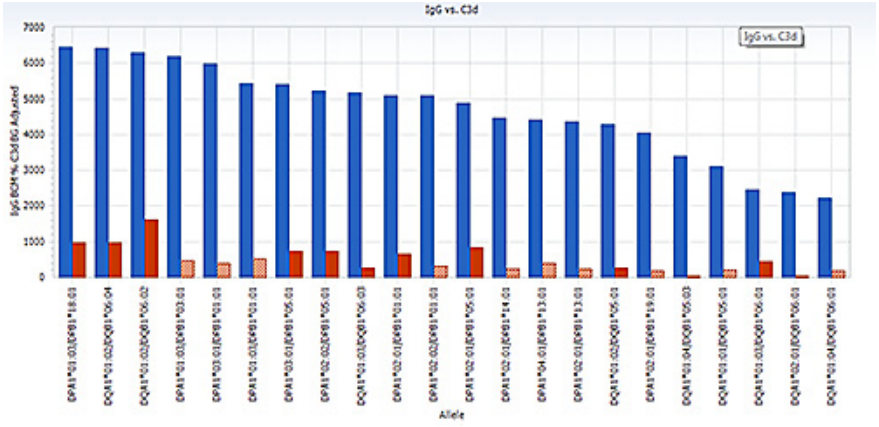
The MATCH IT! software allows the user to generate a graph that gives a direct comparison between LSA IgG and C3d.

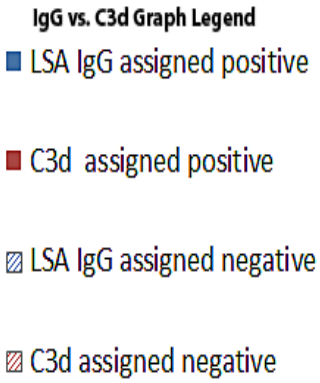
1) Select LSA IgG and C3d data to be graphed. Click on the LSA-IgG sample to select. Hold down the **CTRL** key and click on the C3d sample. As samples are selected they will be highlighted in blue.



2) Right-Click and select **Generate Graph**. All assigned antigens from the antigen window will appear as data points on the graph.

Note: IgG vs C3d Graphs will display Background Corrected MFI in the y-axis and antigens in the x-axis.



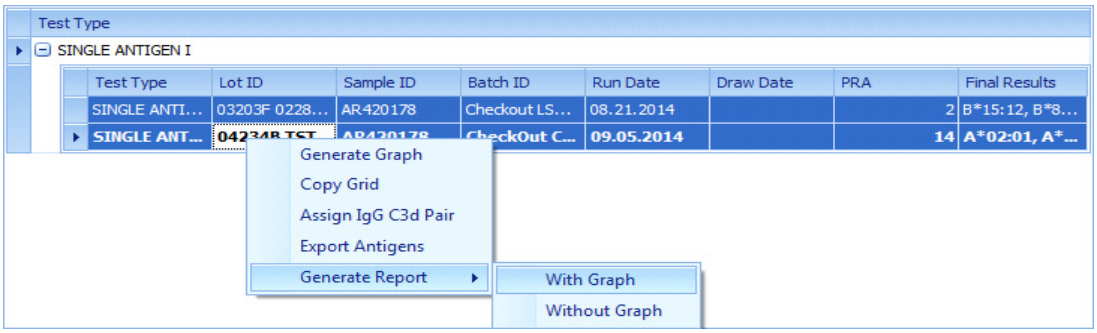


Generating LSA IgG -C3d Reports

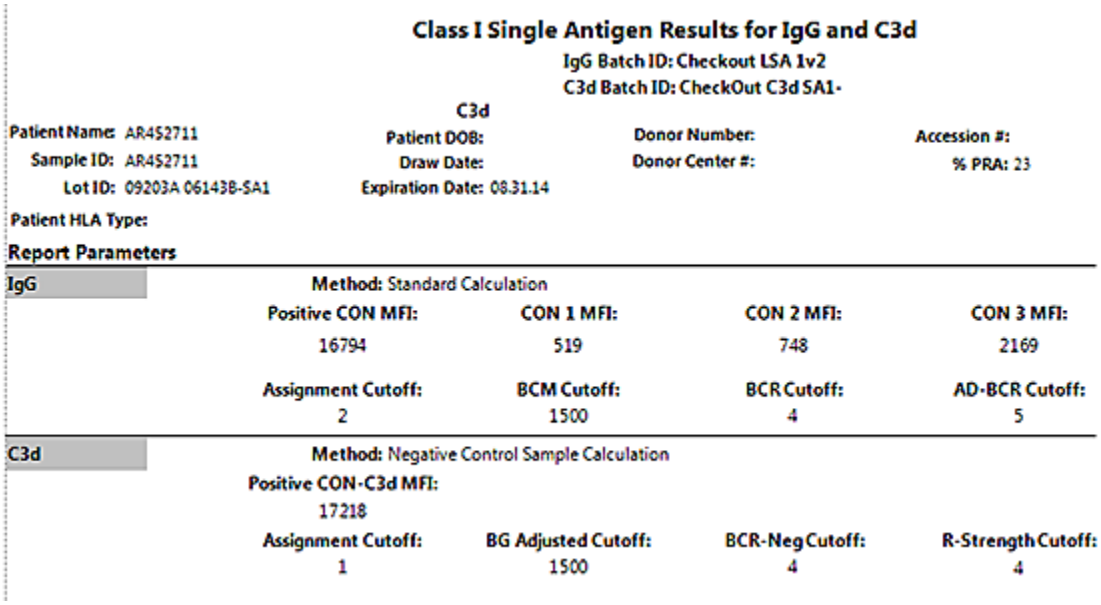
The user can generate a report with LSA IgG data and C3d data from the Sample view screen.

1) Select LSA IgG and C3d data to be reported Click on the LSA-IgG sample to select. Hold down the **CTRL** key and click on the C3d sample. As samples are selected they will be highlighted in blue.

2) Right-Click and select **Generate Graph** from the menu. Select whether or not to include a graph in the report from the sub-menu.



3) The LSA IgG-C3d report will populate a new window.



Class I Single Antigen Results for IgG and C3d

IgG Batch ID: Checkout LSA 1v2
C3d Batch ID: CheckOut C3d SA1-

C3d

Patient Name: AR452711 | Patient DOB: | Donor Number: | Accession #:
Sample ID: AR452711 | Draw Date: | Donor Center #: | % PRA: 23
Lot ID: 09203A 06143B-SA1 | Expiration Date: 08.31.14
Patient HLA Type:

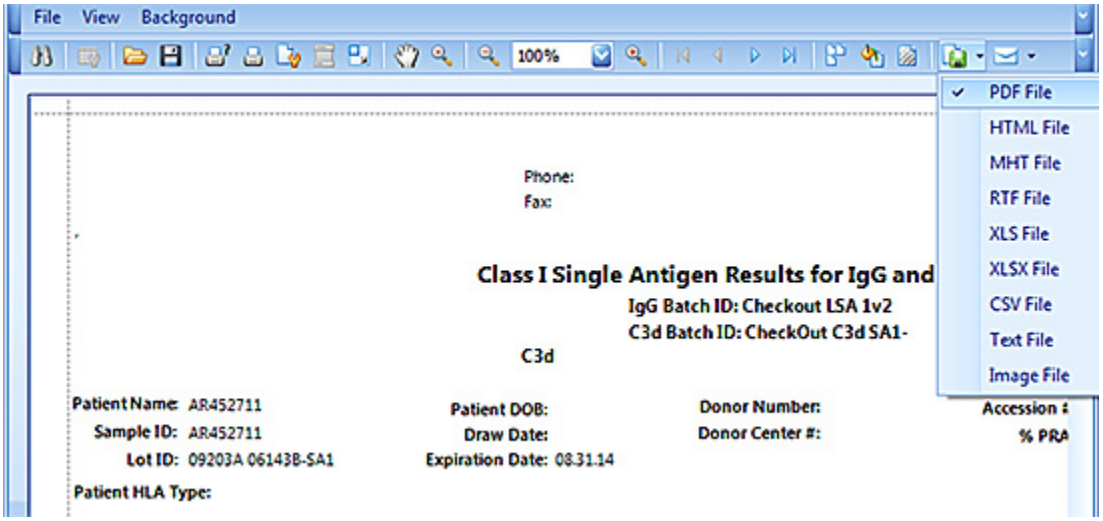
Report Parameters

IgG	Method: Standard Calculation			
	Positive CON MFI:	CON 1 MFI:	CON 2 MFI:	CON 3 MFI:
	16794	519	748	2169
	Assignment Cutoff:	BCM Cutoff:	BCR Cutoff:	AD-BCR Cutoff:
	2	1500	4	5
C3d	Method: Negative Control Sample Calculation			
	Positive CON-C3d MFI:			
	17218			
	Assignment Cutoff:	BG Adjusted Cutoff:	BCR-Neg Cutoff:	R-Strength Cutoff:
	1	1500	4	4

All reports will include IgG and C3d Report Parameters and data will be sorted as follows:

- Positive IgG-Positive C3d
- Positive IgG-Negative C3d
- Negative IgG-Positive C3d
- Negative IgG-Negative C3d

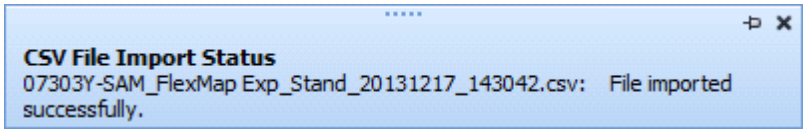
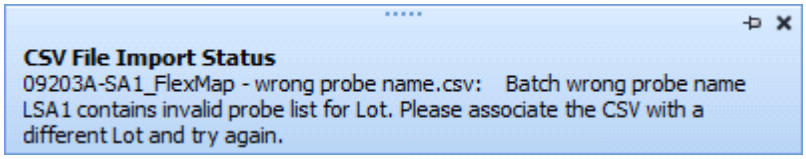
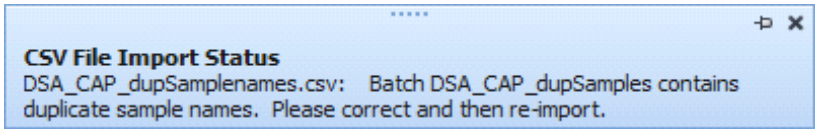
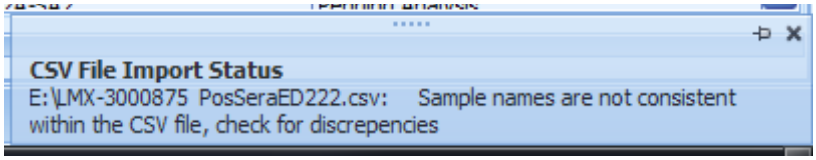
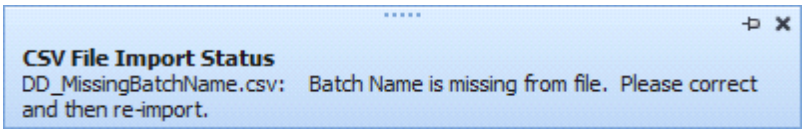
4) Once a report appears on the screen, click the **Export Report** icon in the upper right toolbar.

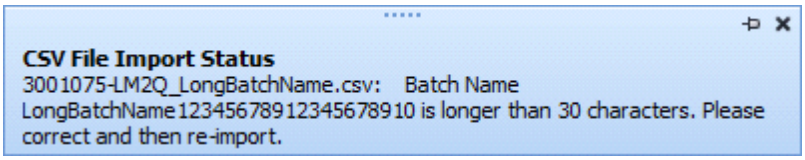
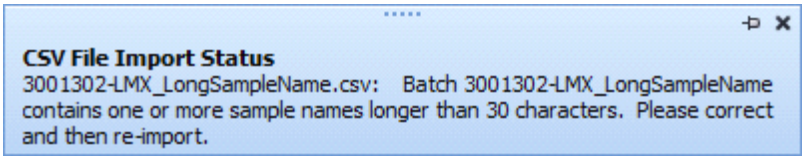
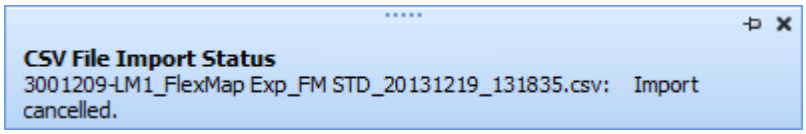
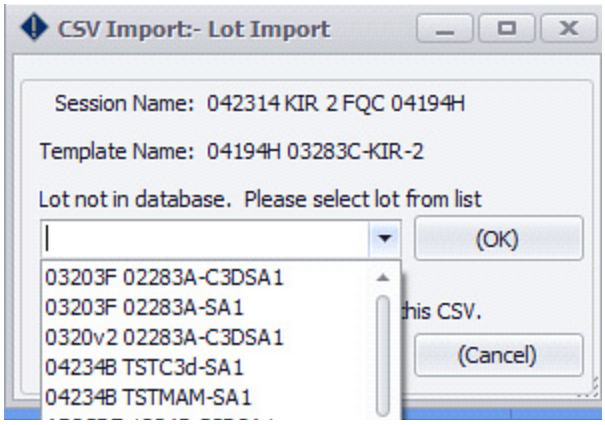
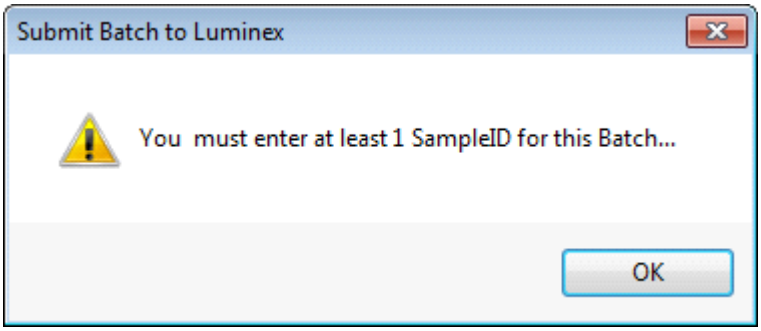


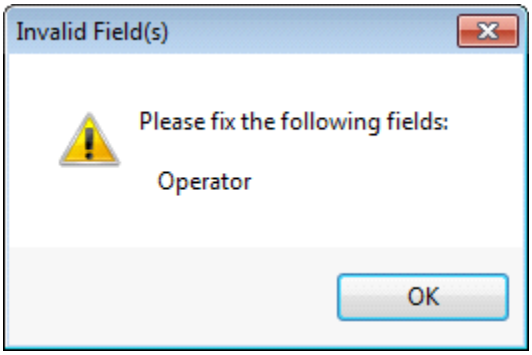
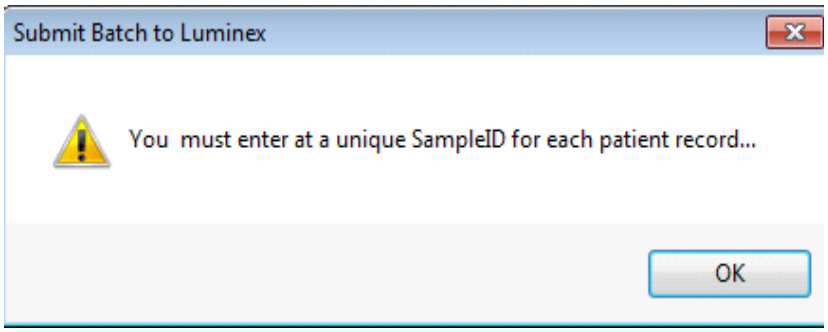
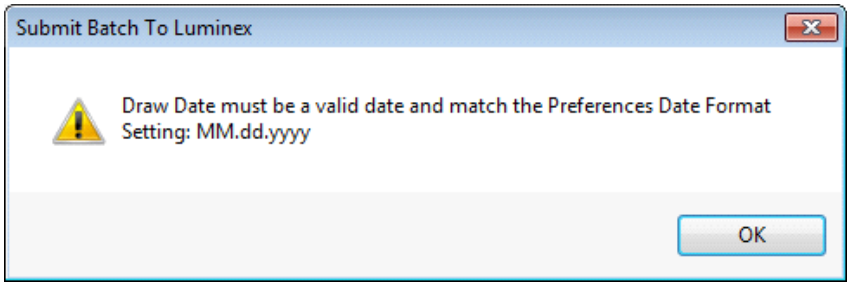
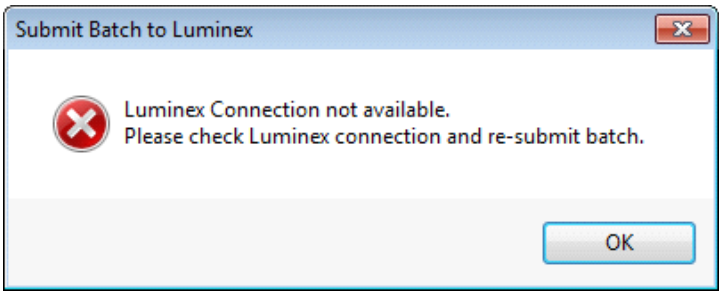
3) The dialog box that appears provides several different options for exporting/saving the report

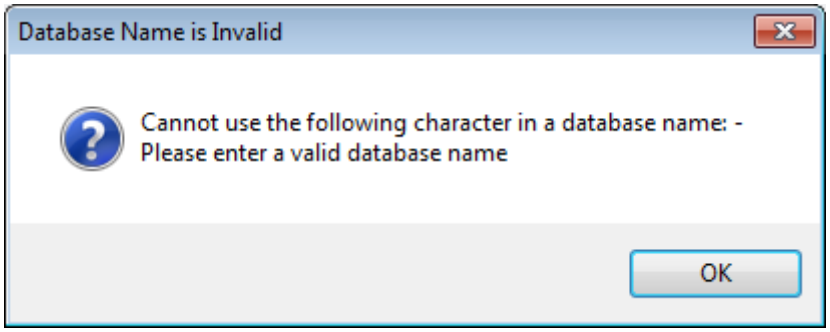
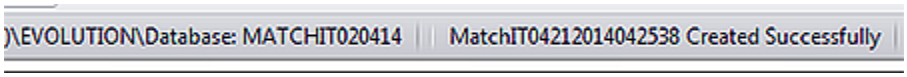
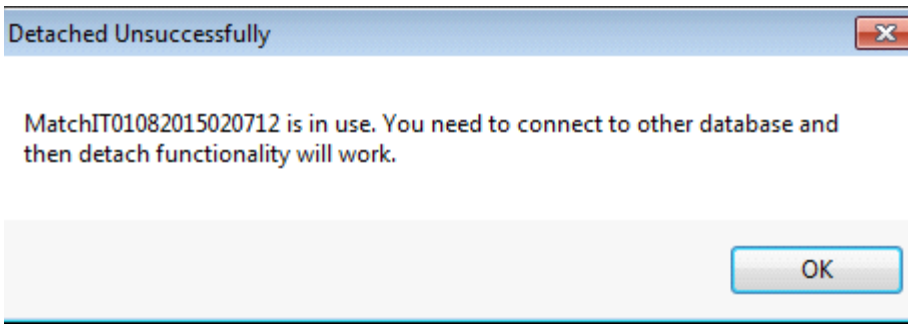
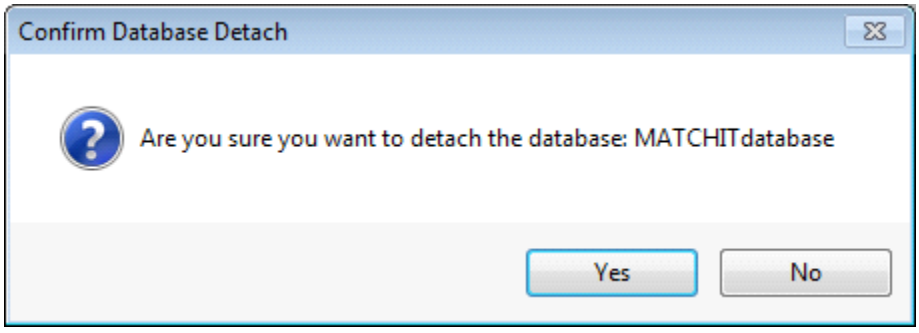
4) Select and **Save** to the chosen location

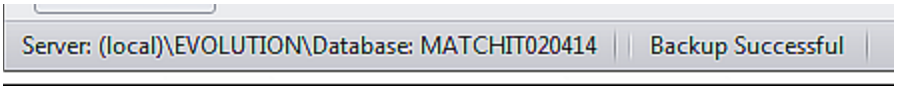
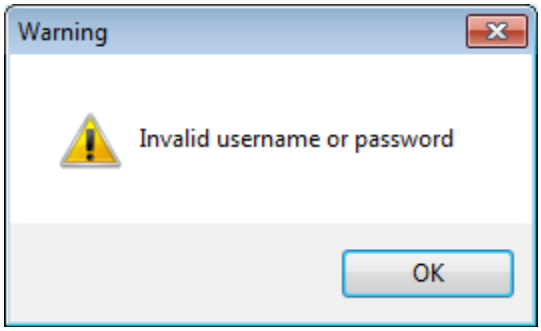
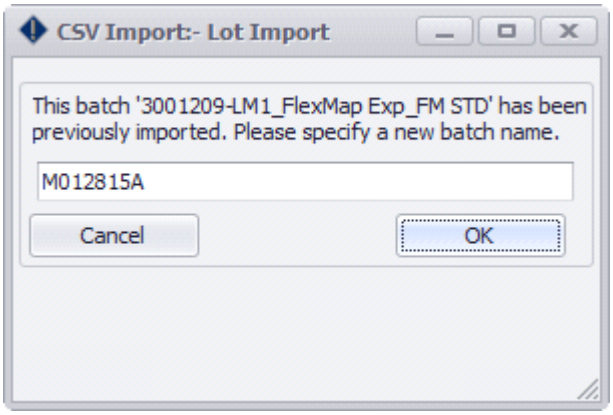
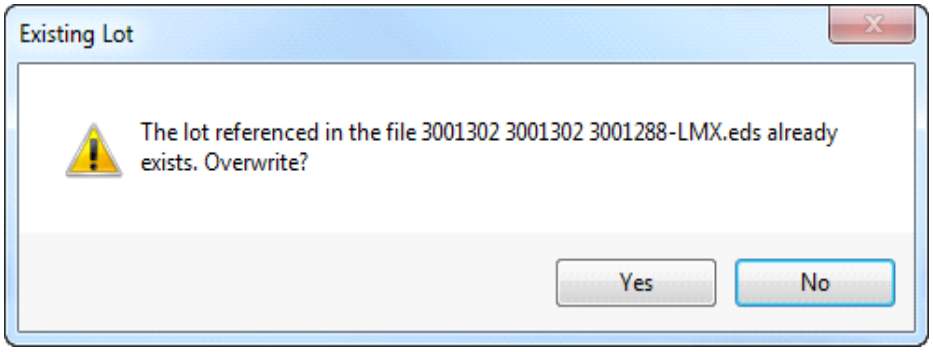
Appendix A: Error Conditions

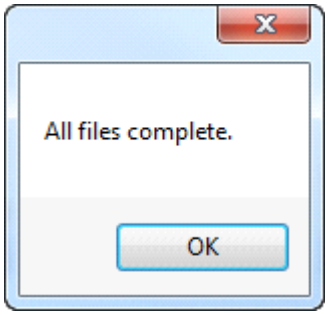
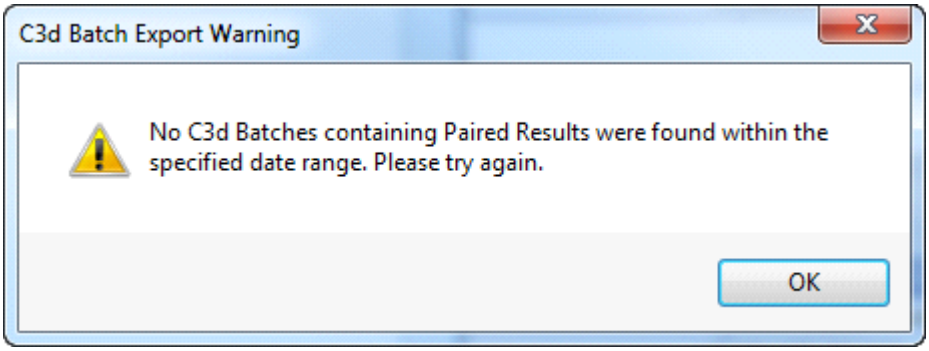
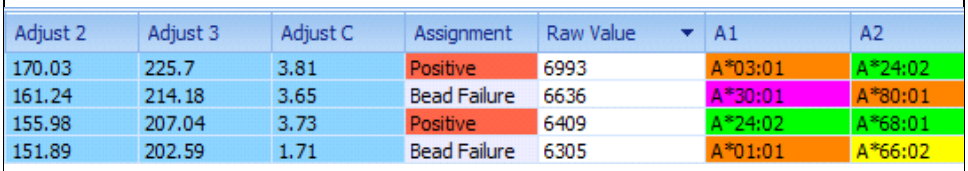
Error Condition	Message
CSV File successfully imported	
Lot selected for import is not correct and has invalid probes	
CSV file contains duplicate sample names	
CSV file contains invalid or inconsis-tent sample names	
CSV file is missing batch name	

Error Condition	Message
CSV file contains Batch name is longer than 30 characters	
CSV file contains sample name(s) is longer than 30 characters	
Batch Import Cancelled	
Lot could not be found in database	
No samples are entered	

Error Condition	Message
Missing Fields	
Duplicate Sample Names	
Invalid date format	
Luminex Connection not available	

Error Condition	Message
Invalid Database Name	
Successful Database Creation	
Detach in-use data-base	
Detach database Confirmation	
Detach database suc-cessful message	

Error Condition	Message
Database Backup successful message	
Invalid Login	
Batch has already been imported into database.	
EDS file already exists in database	

Error Condition	Message
EDS file(s) imported successfully.	
No paired C3d samples found within specified dat range.	
Bead Failure	

Adjust 2	Adjust 3	Adjust C	Assignment	Raw Value	A1	A2
170.03	225.7	3.81	Positive	6993	A*03:01	A*24:02
161.24	214.18	3.65	Bead Failure	6636	A*30:01	A*80:01
155.98	207.04	3.73	Positive	6409	A*24:02	A*68:01
151.89	202.59	1.71	Bead Failure	6305	A*01:01	A*66:02

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(i) The Software will substantially conform to the applicable user documentation and (ii) that the magnetic media on which the Software is distributed and the user documentation (if any) are free from defects in materials and workmanship. If the media is defective, Immucor Transplant Diagnostics, Inc. will replace the Software or provide you with corrected items at no charge provided that the defective item(s) is returned to Immucor Transplant Diagnostics, Inc. within ninety (90) days from the date of purchase. Any misuse or unauthorized modification of the Software will void this limited warranty.

EXCEPT AS SPECIFICALLY PROVIDED HEREIN, Immucor TRANSPLANT DIAGNOSTICS, INC. MAKES NO WARRANTY, REPRESENTATION, PROMISE OR GUARANTEE, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE SOFTWARE, USER DOCUMENTATION OR RELATED TECHNICAL SUPPORT, INCLUDING THEIR QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

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OR COSTS RELATING TO THE LOSS OF PROFITS, BUSINESS, GOODWILL, DATA OR COMPUTER PROGRAMS, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO CASE SHALL IMMUCOR TRANSPLANT DIAGNOSTICS INC.' OR ANY OF ITS LICENSORS' LIABILITY EXCEED THE AMOUNT PAID BY YOU FOR THE SOFTWARE OUT OF WHICH SUCH CLAIM AROSE.

This limitation on monetary damages will not apply to claims relating to death or personal injury which arises out of products deemed to be consumer goods under applicable law. Some states, provinces and other jurisdictions do not allow the exclusion or limitation of implied warranties or limitation of liability for incidental or consequential damages, so the above exclusion or limitation may not apply to you. However, in appropriate jurisdictions, Immucor Transplant Diagnostics, Inc. limits its liability, according to the terms of this Agreement, to the extent permissible at law.
Nothing in this Agreement operates to exclude, restrict or modify the application of any of the provisions of the Trade Practices Act 1974 (Cth) or any equivalent state or territory legislation, the exercise of a right conferred by such a provision, or any liability of Immucor Transplant Diagnostics, Inc. for a breach of a condition or warranty (including but not limited to a condition or warranty in relation to goods or services of a kind ordinarily acquired for personal, domestic or household use or consumption) implied by such a provision.

6. U.S. GOVERNMENT RESTRICTED RIGHTS

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commercial practice, this software agreement, instead of the noted regulatory clauses, shall control the terms of the Government's license.

7. GENERAL

No Immucor Transplant Diagnostics, Inc. dealer, distributor, agent or employee is authorized to make any modification or addition to this Agreement. For use of the Software in North America and Latin America, this Agreement will be governed by the laws of the State of Delaware. For all other countries, this Agreement will be governed by the laws of the country in which the Software was purchased.
For customers: Should you have any questions concerning this Agreement or Immucor Transplant Diagnostics, Inc. ' software use policies, write to Inside Sales and Service,
Immucor Transplant Diagnostics, Inc.
550 West Ave, Stamford, CT 06902.

CONTRAT DE LOGICIEL IMMUCOR TRANSPLANT DIAGNOSTICS, INC.

SI VOUS N'ÊTES PAS D'ACCORD AVEC LES PRÉSENTES MODALITÉS ET CONDITIONS, N'INSTALLEZ PAS LE LOGICIEL ET RENVOYEZ LE EN TOTALITÉ AU PLUS TARD 30 JOURS APRÈS L'AVOIR ACHETÉ, AVEC VOTRE REÇU, POUR VOUS FAIRE TOTALEMENT REMBOURSER.

1. UTILISATION

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ces directives, vous devez d'abord contacter le service suivant: Immucor Transplant Diagnostics, Inc., 550 West Ave., Stamford, CT 06902, USA

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Pendant les quatre-vingt-dix (90) jours qui suivent la date d'achat, Immucor Transplant Diagnostics, Inc. garantit (i) que le logiciel se conformera substantiellement à la documentation destinée à l'utilisateur et (ii) que les médias magnétiques sur lesquels le logiciel est distribué et la documentation de l'utilisateur (s'il y en a une) sont libres de tout vice de matériaux et de main-d'oeuvre. Immucor Transplant Diagnostics, Inc. choisira de vous rembourser le montant que vous avez payé pour le logiciel, ou bien de vous fournir les produits corrigés gratuitement si vous renvoyez les articles défectueux au plus tard quatre-vingt-dix (90) jours après votre date d'achat. Toute mauvaise utilisation ou modification non autorisée du logiciel annulera cette garantie limitée.
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Aucun revendeur, distributeur, agent ou employé de Immucor Transplant Diagnostics, Inc. n'est autorisé à faire des modifications ou des additions au présent contrat. Pour toute utilisation du logiciel en Amérique du Nord et en Amérique Latine, le présent contrat sera régi par les lois du Commonwealth du Delaware. Pour tous les autres pays, le présent contrat sera régi par les lois du pays dans lequel le logiciel a été acheté.
Clients: Si vous avez des questions sur le présent contrat ou sur les politiques d'utilisation des logiciels Immucor Transplant Diagnostics, Inc. , écrivez à: Inside Sales and Service, Immucor Transplant Diagnostics, Inc. , 550 West Ave. Stamford, CT 06902, USA.

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SI USTED NO ESTÁ DE ACUERDO CON ESTOS TÉRMINOS Y CONDICIONES, NO INSTALE EL SOFTWARE Y DEVUELVA ESTE PAQUETE COMPLETO DENTRO DE LOS 30 DÍAS DESPUÉS DE LA VENTA, JUNTO CON SU NOTA, PARA EL REEMBOLSO TOTAL DE SU DINERO.

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Para clientes: Si llegaran a tener alguna pregunta respecto a este Convenio o a las normas del uso de software de Immucor Transplant Diagnostics, Inc., escriban a Servicio y Ventas, Immucor Transplant Diagnostics, Inc. , 550 West Ave., Stamford, CT 06902.